IPN
IRISH PHARMACY NEWS
THE INDEPENDENT VOICE OF PHARMACY

October 2021
Volume 13 ■ Issue 10
PHARMACYNEWSIRELAND.COM



## In this issue:

# BACK TO SCHOOL

Omega 3 fish oil with vitamins, in a delicious SUGAR FREE fruit flavoured smoothie.

*A daily dose of Zomega 3 Smoothie* = *TWO capsules of Omega 3 fish oils*

*No fishy aftertaste -*

*our promise!*


*SONA SUPPORTING*

Children's Health FOUNDATION
Crumlin • Temple Street • Tallaght • Connolly
SUPPORTING CHILDREN'S HEALTH IRELAND

Order direct from Sona on PH: 01 451 5087.
Also available from wholesalers, United Drug and Uniphar.

Sona®
*IRISH VITAMINS*

# Contents



**PUBLISHER**:
**IPN Communications Ireland Ltd.**
Clifton House, Fitzwilliam Street Lower, Dublin 2
**00353 (01) 6690562**

**MANAGING DIRECTOR**
Natalie Maginnis
n-maginnis@btconnect.com

**EDITOR**
Kelly Jo Eastwood:
00353 (87)737 6308
kelly-jo@ipn.ie

**ADVERTISING EXECUTIVE**
Amy Evans: amy@ipn.ie

**EDITORIAL/ EVENTS & MARKETING EXECUTIVE**
Aoife Jackson: aoife@ipn.ie

**CONTINUED PROFESSIONAL LEAD**
Sibongile Swan Mude
swan@ipn.ie

**CONTRIBUTORS**
Dr Damien Lowry | David Fitzgerald
Dr Conor Harrity | Michele Pippet
Dr Caoimhe Hartle | Phyllis Agar
Donna Cosgrove | Dr John Joyce
Dr Edina Moylett | Rachel Dungan
Colm Baker | Colm Moore
Theresa Lowry-Lehnen | Linda Kelly
Dr Catherine Riordan
Professor Connail McCrory

**DESIGN DIRECTOR**
Ian Stoddart Design

**PHARMACYNEWSIRELAND.COM**

**@Irish_PharmNews**

**IrishPharmacyNews**

5


12

22


47

# Foreword

As of September 2nd, Irish pharmacies had administered over a quarter of a million Covid-19 vaccines, including 14,650 vaccinations in the 12-15 age group, highlighting once again the pivotal role they have played during the pandemic.

IPU President Dermot Twomey commended pharmacies saying, "Pharmacies across Ireland have proven their immense value to their communities by their success in the vaccination programme. Since the first vaccines were approved, we have been calling for them to be available in pharmacies and, when called upon by the HSE, the community pharmacy sector has delivered and will continue to do so.

"Pharmacies have made excellent progress across all age groups, with over 170,000 people between the ages of 20 and 39 receiving a vaccine in a pharmacy. The high demand to date amongst younger age groups has highlighted the advantages of community pharmacy involvement in the vaccination programme."

Community pharmacies across Ireland are to be applauded for the way in which they have continuously stepped up to the frontline. Irish Pharmacy News are also keen to acknowledge this, and in doing so last month we launched the search to find the People's Pharmacist for 2021. Since then, nominations have been flooding into our offices, with over 400 at the last count. Make sure you catch the November issue which will profile each of our six deserving finalists.

In our report this issue, we take a closer look at whether or not Ireland is currently facing a pharmacist manpower shortage. Tim Delaney, Head of Pharmacy at Tallaght University Hospital, and Adjunct Associate Professor at the School of Pharmacy and Pharmaceutical Sciences at Trinity College Dublin (TCD) believes the sector is facing a "perfect storm". "One of the big drivers of movement out of retail is dissatisfaction with hours of work, high pressure workloads and lack of breaks; people eating sandwiches off the desk to keep lunchtime services going, for example," he said.

Turn to page 8 to read the full report.

Meanwhile, on page 16 you can read about the recent Lifelong Learning in Pharmacy Conference which took place virtually. The theme for this conference was 'The Journey of Learning'. This theme represents the experience that all pharmacists undertake as they engage in education and adapt to the continuously evolving modern workplace.

I hope you enjoy the issue.

Irish Pharmacy News is circulated to all independent, multiple Pharmacists and academics in Ireland.



## Regulars

# Milestone for Pharmacy

Irish pharmacies have now administered over a quarter of a million COVID-19 vaccines, the Irish Pharmacy Union (IPU) has confirmed, including 14,650 vaccinations in the 12-15 age group remain. With schools re-opening after the summer holidays and strong availability of Pfizer vaccines in pharmacies, pharmacies are available to vaccinate people in the community aged 12 and above who are looking to get vaccinated.

IPU President Dermot Twomey commended the role played by pharmacies in the vaccine rollout, "Pharmacies across Ireland have proven their immense value to their communities by their success in the vaccination programme. Since the first vaccines were approved, we have been calling for them to be available in pharmacies and, when called upon by the HSE, the community pharmacy sector has delivered and will continue to do so.

"The demand for vaccines in pharmacies amongst the younger cohort has been exceptional, with pharmacists administering vaccines to over 50,000 people between the ages of 12 and 19."

"Pharmacies have made excellent progress across all age groups, with over 170,000 people between the ages of 20 and 39 receiving a vaccine in a pharmacy. The high demand to date amongst younger age groups has highlighted the advantages of community pharmacy involvement in the vaccination programme. Getting vaccinated in your local pharmacy is convenient for people in terms of travel and time required. This is particularly the case for many young people, particularly those in school or third level education who might find it difficult to travel to a vaccine centre."

With 992 pharmacies currently offering the Pfizer vaccine, the IPU has reiterated that people can book an appointment directly with their local pharmacy and attend at a set time. "The rising number of cases of the Delta variant means that there is an increased need for pharmacy vaccinations to continue, particularly in relation to younger age groups as they return to school."

Dermot Twomey concluded "the gradual return to normality has come about thanks to the success of the vaccine rollout, helped by the participation of pharmacies across the country. Pharmacies are delighted to be playing a central role in the vaccine rollout."

# Official Opening of New Pharmacy

Allcare Pharmacy recently opened their latest store which had a massive refurbishment in Bunclody, Co. Wexford.

Pictured at the opening of Loftus Allcare Pharmacy, Bunclody are Anne, Michelle, Mary, Mark Pattison, Pharmacist, Lee Chin, Cllr. Barbara Ann Murphy, Chairperson, Wexford Co. Council, Kenny Robertson, Director of Retail, Maureen and Rachel

Said a company spokesperson, "A massive thank you to everyone involved in the launch and we look forward to serving the local community from our newly renovated pharmacy."

The pharmacy offers a comprehensive range of products and services and is far more than just a traditional business of its type.

Among the wide range of services offered by the pharmacy include blood pressure checks, a prescription testing service, asthma checks, diabetes health check, general health checks and a 24-hour blood pressure monitoring service.

Opening the new store was Wexford Senior Hurling star, Lee Chin, alongside the Cathaoirleach of Wexford County Council, Cllr Barbara-Anne Murphy.

# Medicine Shortages

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

The Health Products Regulatory Authority (HPRA) has been notified of a shortage of the following products:

- Amitriptyline 25mg Film Coated Tablets - PA0126/041/001
- Astilin 10mg Tablet - PA23163/001/001
- Bendroflumethiazide 2.5mg Tablets - PA22749/021/001
- Dalacin 2% Vaginal Cream - PA0822/119/002
- Innohep 8,000 IU in 0.4 ml, Solution for Injection - PA0046/060/012
- RoActemra 162mg Solution for Injection in Pre-Filled pen - EU/1/08/492/009-10
- Rosuvastatin 5mg Film Coated tablets - PA2315/068/001
- Rosuvastatin 10mg Film Coated Tablets - PA2315/068/002
- Zofran 4 mg/5ml Syrup - PA0896/036/003

The following shortages have been resolved and supply has resumed to the Irish market:

- Iopidine 1%w/v Eye Drops, Solution - PA0896/014/002
- Glyceryl Trinitrate 5 mg/ml Sterile Concentrate - PA0822/204/001
- OxyNorm Dispersa 5mg Orodispersible Tablets - PA1688/006/007
- Palladone SR 2mg prolonged release capsules - PA1688/007/007
- Telmisartan 40mg Tablets- PA2315/014/002
- Zofran 8mg/4ml Solution for Injection or Infusion - PA0896/036/002

## High blood Pressure Risk Factor

The number of adults aged 30-79 years with hypertension or high blood pressure has increased from 650 million to 1.28 billion in the last thirty years, according to the first comprehensive global analysis of trends in hypertension prevalence, detection, treatment and control, led by Imperial College London and the World Health Organization (WHO), and published in The Lancet. Nearly half these people did not know they had high blood pressure.

The UK was one of the top ten countries with the lowest prevalence of high blood pressure among women in 2019 at 23 per cent while in Ireland this figure was 26.6 per cent.

The study found that the country with the highest prevalence of high blood pressure in men was Paraguay at 62% compared to 22% in Eritrea which had the lowest prevalence among men.

In Ireland the prevalence of high blood pressure among men in 2019 was 38.2%

High blood pressure or hypertension significantly increases the risk of heart, brain and kidney diseases, and is one of the top causes of death and disease throughout the world. It can be easily detected through measuring blood pressure, at home or in a health centre, and can often be treated effectively with medications that are low cost.

The study, conducted by a global network of physicians and researchers, covered the period 1990-2019. It used blood pressure measurement and treatment data from over 100 million people aged 30-79 years in 184 countries, together covering 99% of the global population, which makes it the most comprehensive review of global trends in hypertension to date.

The study also indicated that more than half of people (53% of women and 62% of men) with hypertension, or a total 720 million people, were not receiving the treatment that they need.

# Pharmacists Voice Fears over 'Wastage'

A group of pharmacists working in mass vaccination centers across the country have written to Taoiseach Micheál Martin and Health Minister Stephen Donnelly warning that thousands of Covid-19 vaccines will go to waste despite many still waiting to be vaccinated.

The group of 16 tried to find a way to redirect vaccines to pharmacies where there are waiting lists but it was not successful, of course.

The letter from pharmacists, some of whom work with HSE, protested the plans and said it will result in thousands of wasted doses. The group called for diplomatic efforts to be made to send the vials overseas to vaccine-shorted countries.

They stated, "As pharmacists working in mass vaccination centers in Ireland, we wish to express our frustration with the National Immunization Bureau's policy to allow the destruction of the Janssen and Astra Zeneca Covid 19 vaccines, while millions of people around the world do not have access to vaccines.

"Our point of view, outlined here, is widely shared by clinical managers, site managers, doctors, nurses and many others who work with us in mass vaccination centers," says the letter, which was also sent to HSE.

"Thousands of doses of Janssen vaccines have already gone or are about to expire, despite repeated requests to mass vaccination centers to distribute them to municipal pharmacies. There is a cohort of Irish citizens who only want a Janssen vaccine, this has now been denied to them and as a result they remain unvaccinated."

"Please stop this unnecessary waste and allow vaccines to be used in some less fortunate countries where vaccines are not readily available," their letter continued.

In a statement, the HSE said it does not expect significant quantities of unused vaccines.

"The Department of Health is responsible for policy decisions on vaccines in Ireland and is looking into the issue of donating to other countries and the HSE is supporting this process.

"Community vaccination centers are completing their cohorts and therefore the remaining vaccines are still unknown. The expiration dates are 90 days from the thaw or date of delivery to community vaccination centers and a relatively small number will remain, "he said.

# Two Decades of Pharmacy Success

Early last month, Meaghers Pharmacy Managing Director and Pharmacist, Oonagh O'Hagan celebrated a milestone, marking 20 years in pharmacy business.

Oonagh O'Hagan, Managing Director, Meaghers Pharmacy Group


Commenting on her social media, she commented, "On this day 20 years ago I signed for and got the keys of my very first pharmacy from my former tutor, Pierce Meagher here on Baggot Street in Dublin.

"Since then my incredible team and I have grown and transformed our business of nine pharmacies serving not only nine physical communities here in Dublin but a growing online community across Ireland and shipping to 58 countries all across the world now.

"Thank you to all of my team Meagher's Pharmacy Group, all our amazing customers, suppliers, partners and collaborators for your support to my business and to me personally over the last 20 years.

"What a journey it's been. Thank you for being part of the ups and sharing in our success and for also being part of our support network on the many down days too.

We wouldn't be here to mark this day without your never ends support and loyalty.

"Here's to the next chapter," she added.

# Importance of Pharmacy has Increased

The importance of community pharmacies has increased throughout the pandemic according to new research from B&A. The study, published by the IPU, found that with overall visits to GPs decreasing during the pandemic, pharmacies have grown in importance. 39% of people now see their pharmacist as their most important healthcare professional.

Dermot Twomey, President, Irish Pharmacy Union

The 2021 edition of the Irish Pharmacy Index is the 15th annual study to quantitively measure public attitudes to pharmacy in Ireland.

**Key findings of 2021 study include:**

- **The number of people citing pharmacists as their most important healthcare provider has increased by almost a third;**
- **The majority of people (54%) visited the GP less often throughout the pandemic period, with many consulting with their pharmacist instead;**
- **Pharmacists play a much greater role in the healthcare of younger adults. Someone under the age of 25 is four times more likely to have been to the pharmacy in the past week than a GP;**
- **Up to half (48%) of the adult population indicated that the pandemic has either had some or a significant impact on their health with the biggest impact being on younger adults;**
- **85% of people see pharmacies as highly accessible and 57% believe they are increasing in relevance; and**
- **There is clear support for pharmacies expanding the range of services they provide, including 88% favouring the availability of vaccines in pharmacies.**

Commenting on the findings, IPU President, Dermot Twomey said, "The role of the community pharmacy has been expanding and increasing in importance for many years. This accelerated during the pandemic as pharmacies kept their doors open during each lockdown. With people visiting GPs less, or GPs favouring virtual appointments, the accessibility of pharmacies is driving healthcare in our communities."

The report found that 85% of people find pharmacies accessible compared to 51% for GPs and just 13% for hospitals. Furthermore, the longer opening hours typically offered by pharmacies were recognised, with 75% agreeing that pharmacies are available at a time that suits compared to just 31% for GPs.

Mr Twomey welcomed the exceptionally high levels of trust (97%) patients have towards their pharmacies by patients, "Pharmacists pride themselves in their personal approach to healthcare and supporting patients. The direct personal interaction allows us to provide valuable advice to patients in a quick and convenient way."

Public support for expanding the role of pharmacies is very strong with 95% favouring pharmacists being allowed to prescribe medications for minor ailments. "The pharmacy profession stepped up during the pandemic in a big way. The sector has now administered more than 215,000 COVID-19 vaccines in just two months. Prior to that, when called upon and empowered to do so, we extended and repeated prescriptions for patients for up to nine months when other healthcare providers weren't available, to ensure safe continuation of patients' medication and to help manage their existing health conditions. Both are examples of how increasing the role of pharmacies can rapidly lead to successful results."

Mr Twomey concluded by calling for a concerted government effort to maximise the value of the pharmacy sector in post-pandemic healthcare, "We are all optimistic that the crisis of the pandemic will recede in the coming months. Now is the time to plan for how healthcare will operate in future. Ireland's 1,800 community pharmacies have the ability and experience to provide more services in order to help ensure the implementation of the Sláintecare goal of 'care in the community'.

"The types of services which community pharmacists are ideally positioned to deliver include a pharmacy-based Triage Programme including a Minor Ailment Scheme and for women to be allowed to access contraception directly from their community pharmacist without prescription.

"These services are being offered by pharmacies in other countries and the approach is working. It's more efficient for patients and is more cost effective for the State.

"The public wants this and pharmacists want this. All we need now is for the government to take notice and to start availing of this huge potential."

# Vaccine Hesitancy Drops

Covid-19 vaccine hesitancy has dropped by 36 points over the past 10 months, according to the latest research carried out by Ipsos MRBI for the Irish Pharmaceutical Healthcare Association (IPHA).

Last October, when IPHA began tracking public appetite for Covid-19 vaccines, 12% of people said they would not get vaccinated for the disease. In the same month, 33% said they were unsure. By this month, the proportion of people who said they will not get vaccinated for Covid-19 had dropped to 5%. Just 4% are unsure.

In the 18 to 34-year-old cohort, 86% either intend to get vaccinated for Covid-19 or have already received a vaccine for the disease. Last October, 19% of people in that age cohort said they would refuse a vaccine against 7% this month. A further 32% of 18 to 34-year-olds said they were unsure about vaccination last October compared with 8% this month.

In the 18 to 24-year-old cohort, 10% said they were unsure about getting a Covid-19 vaccine against 15% last month. In the same age cohort, 4% said they would refuse to get vaccinated for the disease – the same proportion as last month.

Overall, 91% of people either intend to get vaccinated or have already received a vaccine for the disease. The results show that 5% of people will take a Covid-19 vaccine. But when combined with the cohort that has received at least one Covid-19 vaccine dose, or 86% of the sample*, that number rises to 91%.

Bernard Mallee, Director of Communications and Advocacy at IPHA, said, "No vaccine is manufactured start-to-finish in one factory or even in one country. Ingredients can come from all over the world and, often, multiple sites are involved in production. So, it is vital that the integrity of the global supply chain is maintained."


# THEALOZ® DUO

TREHALOSE 3% I HYALURONIC ACID 0.15%

MEDICAL DEVICE

- ✓ Protects – Hydrates – Lubricates – Repairs
- ✓ 100% Preservative FREE
- ✓ Clinically PROVEN*
- ✓ Fixed combination of Hyaluronic acid and Trehalose for synergistic action
- ✓ Suitable for all Dry Eye sufferers, including contact lens wearers

BEST EYE CARE PRODUCT IPN Thealoz Duo

Now available on the GMS

Abak® System
The most widely used preservative-free bottle in the world

0% PRESERVATIVE

THEAPAMEX
let's open our eyes

TheaPamex Ltd., 14 Moneen Business Park, Castlebar, Co. Mayo
Phone: 094 925 0290

www.theapharma.ie

# A 'Perfect Storm'

**The past 18 months have had an unforgettable impact on our health service. The pandemic has brought with it innumerable challenges for healthcare workers, including hospital and community pharmacists.**

An even more shifting, unsteady landscape has emerged within healthcare. Niamh Cahill reports.

Against this backdrop, hospitals are struggling to recruit pharmacists and community pharmacies are crying out for locums. Yet, pharmacist numbers in Ireland have never been higher.

The apparent incongruity begs several questions. Does a pharmacist manpower shortage exist? What are the factors influencing the pharmacist workforce? And what, if anything, is being done to ensure pharmacists are attracted to and remain in the profession?

> "It doesn't help when a potential recruit working in the UK is now being charged a large fee to register under the third country route [in place since Brexit]. Why come home and have all that cost added, when you get paid just as well in UK and having lower living costs?"
>
> *Tim Delaney*

Tim Delaney, Head of Pharmacy at Tallaght University Hospital, and Adjunct Associate Professor at the School of Pharmacy and Pharmaceutical Sciences at Trinity College Dublin (TCD) believes the sector is facing a "perfect storm".

"One of the big drivers of movement out of retail is dissatisfaction with hours of work, high pressure workloads and lack of breaks; people eating sandwiches off the desk to keep lunchtime services going, for example," he said.

An IPU paper published in January 2019 found low job satisfaction levels among community pharmacists, with a rating of 5.4 out of 10.

It concluded that community pharmacy was at a crossroads and underlined the need to return "a sense of optimism and of the possibility for change to practicing community pharmacists".

On top of that, according to Delaney, "many hospitals are struggling to recruit pharmacists and there are large numbers of vacancies".

"It doesn't help when a potential recruit working in the UK is now being charged a large fee to register under the third country route [in place since Brexit]. Why come home and have all that cost added, when you get paid just as well in UK and having lower living costs?"

**Crisis in Leadership**

Furthermore, he believes a "crisis in leadership" is impacting the profession, created by the Pharmacy Act 2007, which transformed the PSI into a regulator, leaving the profession without a leadership body.

Ways in which the profession could be used and transformed within healthcare are also being ignored, he said, while manpower planning is non-existent.

"There is no sign Government understands what is possible if the profession is utilised better. Government does not

see pharmacy in the way UK does," he warned.

"There is no enthusiasm in the HSE for real transformation of hospital pharmacy including the development of an advanced practice framework."

As an example, he referenced a deal agreed between the Department of Public Expenditure and Reform (DPER) and the Hospital Pharmacists Association of Ireland (HPAI) in October last year, which has since "stagnated".

**Pharmacy Numbers at an all time High**

Last year 320 pharmacists were added to the professional register, bringing the total number in 2020 to an all-time high of 6,767, up from 6,506 in 2019 and 6,246 in 2018.

Despite this shortages persist and more pharmacists are needed in both community and hospital pharmacy.

What's more, there is a fear that Brexit could lead to a fall in pharmacist numbers here long-term.

According to Delaney, the UK has for many years been "a critical source of pharmacists for Ireland".

He cited a 2018 analysis of pharmacist workforce capacity in Ireland over the past 15 years, published by McMahon, Bermingham, and Griffin of UCC School of Pharmacy, which illustrated our reliance on overseas-trained pharmacists.

It found that the workforce is "highly dependent on new registrants applying via the EU mutual recognition route, predominantly from the UK".

It revealed that pharmacist numbers increased by 90 per cent over the last 15 years and that 57 per cent of new registrants qualified via the EU route, mainly through the UK.

PSI registrants via the national route were 27-56 per cent of total additions annually, it found, while Ireland's output of pharmacy graduates is 40 per cent lower than the UK.

**Brexit has been anything but smooth**

While the supply of drugs and medicines here has remained largely unaffected, the same cannot be said for the movement of pharmacists between both jurisdictions.

New barriers are already having an impact here. This is evidenced in data from the Pharmaceutical Society of Ireland (PSI).

The PSI has processed just 29 UK (including Northern Ireland) Third Country Qualification Recognition (TCQR) applications processed to date in 2021.

But a spokesman for the PSI qualified the figure with the proviso that due "to time of conferral of qualifications, both in Ireland and the UK, the upcoming end of year registration period is the busiest time of application for new graduates to the PSI".

A look at the number of UK qualified pharmacists registered with the PSI in recent years tells its own story.

In 2018 the figure was 127, in 2019 it rose to 164. But in 2020, during the pandemic, the number fell to 106.

The fees applicable to UK based graduates to practice as pharmacists in Ireland since Brexit are being criticised as a deterrent to recruitment here.

"Brexit will certainly pose problems for pharmacy workforce numbers in Ireland when you consider the large numbers coming onto the register here, that trained in the UK," according to Delaney.

"I have heard from pharmacies near border areas that this has already proven to be a deterrent to pharmacists living and qualifying in Northern Ireland, who might otherwise have considered working in this jurisdiction. Reducing that fee to a more nominal level might be a practical start."

The 2018 workforce capacity analysis, mentioned earlier warned that "any interruption to mutual recognition of pharmacists between the EU and UK, as a result of Brexit, would significantly affect the capacity of pharmacy services in Ireland.

**Review of Capacity**

"In order to meet global trends of the increasing number of patients needing access to pharmacy related services and diversification of pharmacist roles, ongoing review of capacity in pharmacy is essential."

A PSI spokesman said a review is underway into the entire TCQR process "with the intention of introducing a new system of recognition that would be a more effective and efficient route for all third country applicants seeking to practice in Ireland".

The pandemic and Covid-related work has to date delayed the review's progress, however, the spokesman added.

The PSI operates three routes for first time pharmacist registration. The route through which a pharmacist can apply to the register is based on where their pharmacy qualification was awarded.

Pharmacists from Non EU/EEA countries must pay an application fee of €1,500 and another €540 registration fee under the TCQR process.

The same rules apply to pharmacists from Great Britain and Northern Ireland. But the fee does not apply in certain circumstance.

These include if a UK professional qualification was recognised in Ireland before 31 December 2020, if an Irish professional qualification was recognised in the UK before the same date and if an application was in the process of being recognised at the end of the 31 December transition period deadline last year.

After this date, however, there is no exemption, it is understood, and the fee applies.

"The current streamlined process for recognition of UK qualifications obtained prior to the Brexit date is facilitated by a legislative amendment made to the PSI's registration rules. The PSI Council put this streamlined approach in place on the basis that the UK qualification would have been previously recognised under the Professional Qualifications Directive to and this would have removed the requirement for the steps involved in qualification recognition," a spokesman explained.

They added that the PSI "continuously monitors the education and training requirements for pharmacists in the UK, and divergence from the existing EU-aligned programmes may require the Council to reassess the route of recognition".

Kerry based pharmacist Dr Jack Shanahan said Brexit would have a long term impact on pharmacist manpower in Ireland.

**Factors at Play**

"But in the short term, we already have a shortage of manpower in community pharmacy. Brexit is exacerbating it, but it's not the major factor."

Indeed, Brexit is but one factor. Many others are at play.

Colm Devine, Chief Pharmacist at Letterkenny Hospital, told IPN that it is becoming increasingly difficult to fill pharmacist vacancies within hospitals.

"We closed a campaign for senior pharmacists in April for which we had eight vacancies. We got just three eligible applicants, two of which were internal. It makes the prospect of any service development extremely challenging.

"I had hoped there would be interest from across Northern Ireland but the PSI's third country registration process, courtesy of Brexit, requires a gouging €2,000 upfront to get registered here

"We closed a campaign for senior pharmacists in April for which we had eight vacancies. We got just three eligible applicants, two of which were internal. It makes the prospect of any service development extremely challenging"

*Colm Devine*

> "I experienced first-hand the difficulty getting locum and part-time pharmacist cover. This was one of my considerations in pursuing a career change"
>
> *Michael McCarthy*

now. As if recruitment wasn't hard enough already.

"The other thing we could really do with is structured training posts like we see in the hospitals in Dublin and Cork and of course right across Northern Ireland."

Others have blamed poor entry level salaries for HSE pharmacists on recruitment problems. The entry level salary scale for a qualified pharmacist is €34,000. Meanwhile, inadequate support and postgraduate training schemes at some hospitals have been attributed to poor take up.

Elsewhere, in Scotland, Wales, England, and more recently in Northern Ireland, it has been reported that GP recruitment of pharmacists has resulted in a shortage of pharmacists in community pharmacies.

This is a problem not experienced in the Republic, as there are few if any GP pharmacist roles. Although, such a role has been examined here as part of drug safety initiatives and is supported by many GPs.

**Squeeze on Manpower**

Secretary General of the IPU, which represents community pharmacists, Darragh O'Loughlin, said it is aware of a "squeeze on pharmacist manpower at the moment that is affecting pharmacy businesses across the country, with many permanent vacancies going unfilled and a scarcity of locum cover."

Work was underway to help retain community pharmacists but since the emergence of Covid-19 it remains suspended, O'Loughlin said.

"In the hope of staunching the outflow of pharmacists from community pharmacy into other career options and recognising the need to attract and retain good people in community pharmacy, since 2018 the IPU has been engaged in a forum with the Department of Health, HSE, PSI, IIoP, Appel and the Schools of Pharmacy, which was established to identify and agree measures to improve the attractiveness of community pharmacy as a career.

"This work is informed by previous IPU research into the pharmacists' perspectives of community pharmacy and the primary satisfiers and dissatisfiers of working in community pharmacy.

"However, as a result of the Covid-19 public health emergency and need to focus resources on the pandemic response the work of the forum has been in abeyance. We are working to reconvene the forum so that we can again renew our efforts to enhance the attractiveness of community pharmacy as a career."

So what are the factors affecting pharmacist recruitment here?

Two years ago, according to Shanahan, locums for community pharmacy were very difficult to source at reasonable rates.

Last year, because of the pandemic and lockdown, locums were largely unneeded as few pharmacists took time off.

This year, with restrictions eased, the situation changed once again and locums were in high demand. Despite extremely high rates on offer, some pharmacists still couldn't source a locum, however, he said.

Shanahan believes community pharmacy had changed enormously in recent years, moving from being a drug focused to a patient focused profession.

"Each patient requires more work. Every prescription requires extra time to look after because you're giving a more holistic, patient approach. That takes time and effort."

The profession has become overburdened and overly-bureaucratic, factors which are steering pharmacy graduates in other directions, he said. In addition, others are leaving the profession.

"A lot of our time is wasted trying to contact suppliers about drug shortages or trying to contact prescribers about prescription issues. This is got worse due to Covid as GPs are a lot busier on the phone now than they were before.

"The reality is we don't have enough community pharmacists coming into the profession at the moment."

Pharmacist Michael McCarthy completed a survey on this subject in 2019 along with pharmacist James Vaughan as part of a Masters course in health economics at NUIG.

**Pharmacist Recruitment Survey**

McCarthy currently works as a health economics and outcomes research consultant at MAP BioPharma Limited. But he used to be a full-time supervising community pharmacist.

He now locums in community pharmacy to "stay in touch" with developments.

"Until Sept 2019, I was a supervising pharmacist in a pharmacy in Cork. I experienced first-hand the difficulty getting locum and part-time pharmacist cover. This was one of my considerations in pursuing a career change," he said.

"On my course in NUIG, four of the 16 or so students were also pharmacists who had decided to change career path. And anecdotally, I knew of many other pharmacists who had left community pharmacy in recent years. This was the inspiration for the survey that myself and James carried out."

The research yielded responses from 1,570 pharmacists and was distributed to around 6,000 pharmacists.

Titled "A Survey of Pharmacist Career Paths", it concluded that while pharmacy as a career is evolving the community pharmacy sector was not.

"Current issues with workforce shortages need to be addressed as a matter of urgency. With uncertainty surrounding Brexit also on the horizons, innovation needs to be swift and effective. The sector needs to be revitalised and has to become a more challenging, stimulating and progressive career choice. Higher wages alone are insufficient to attract pharmacists to community pharmacy," the authors warned.

For McCarthy, the onerous administrative burden from the PSI and HSE were other factors in his decision to switch career.

"There is also a distinct lack of development in community pharmacy in Ireland. The role of the pharmacist hasn't really been allowed to grow or expand. The opportunity for career progression is important to me and career progression plateaus very early in community pharmacy. As a supervising pharmacist, the difficulty arranging locum cover was another constant struggle. It is also a very isolated profession in a lot of cases. Most pharmacies only have a single pharmacist on duty at any time. A lot of these issues are connected."

He believes that minimising paperwork and the overall administrative burden would help to make the career more attractive, as well as expanding the services offered at pharmacies.

**Double Edged Sword for Pharmacy**

The pandemic has been a "double edged sword" for community pharmacy, he argued.

On the one hand, it led to the electronic transfer of prescriptions from GPs to pharmacies and the suspension of end of month reimbursement claims using paper.

The Covid-19 vaccination programme by pharmacists, which has seen 250,000 vaccines administered by pharmacists, has also demonstrated the convenience of pharmacies, McCarthy added.

But, he warned that the crisis had turned Government attention away from the challenges facing community pharmacy.

Indeed, many pharmacists believe there is distinct lack of leadership within the Department of Health on pharmacy issues, without any attention being paid to the future of pharmacy in Ireland.

For many years there has been no chief pharmacist post at the Department, for example.

Shanahan questioned the focus on pharmacy manpower planning, saying there is little evidence any such work is taking place.

"There is no individual in the Department of Health charged with looking at community pharmacy for example," he said.

# ELAVE

SENSITIVE CARE

# Baby

## Nourish and Protect Sensitive baby skin

Elave sensitive skincare is paediatrician approved for newborns and for use during pregnancy.


ghp Healthcare & Pharmaceutical Awards

Awarded Best Cruelty Free Skincare by Global Health Pharma 2021

J Gardiner FOUNDER

MADE IN IRELAND

PETA Cruelty-Free and Vegan

www.GardinerFamilyApothecary.com

# Sale of Wholesaler to have 'No Impact' on Staff

The sale by US McKesson Corporation of United Drug wholesale group and Lloyds Pharmacy businesses will not have "any impact" on staff, according to a spokeswoman for United Drug.

Brian Tyler, Chief Executive Officer, McKesson

In a statement to Irish Pharmacy News (IPN), a spokeswoman said McKesson had agreed to sell certain European businesses to the German, privately-owned PHOENIX group, and that a number of its Irish businesses were part of the deal.

"The transaction is expected to close in 2022, subject to the required regulatory approvals," the spokeswoman confirmed.

"Ireland is part of this deal, but it will be business as usual and we do not anticipate any impact to United Drug, TCP Home care, Median Healthcare Services, and LloydsPharmacy businesses in Ireland."

The PHOENIX group, owned by the Merckle family, is a leading integrated healthcare provider in the European healthcare sector, with over 25 years' experience serving customers, patients, and partners across Europe.

The sale includes McKesson Europe businesses in France, Italy, Portugal, Belgium, and Slovenia.

The remaining European businesses in the UK, Norway, Austria, and Denmark are not included in the transaction and will continue to be operated by McKesson.

However, the company is continuing to explore "strategic alternatives for all remaining businesses in the UK, Norway, Austria, and Denmark," according to a statement.

McKesson will retain its minority equity stake in the company's Germany joint venture with Walgreens Boots Alliance.

"Today's transaction marks an important step in advancing McKesson's commitment to streamline the business and prioritize investments in the areas where we have deep expertise and are central to our long-term growth strategy," said Brian Tyler, Chief Executive Officer, McKesson.

"We are confident that under the PHOENIX group's strong leadership, the businesses included in this agreement will be well-positioned for the future to compete more effectively and better serve customers. We will continue to operate our remaining businesses in the UK, Norway, Austria, and Denmark while also exploring a strategic path forward to fully exit the European region. Our goal is to accelerate our growth strategies, becoming a more focused organization and enabling our mission to improve care in every setting."

Kerry based pharmacist Dr Jack Shanahan described the sale as "the way things are going" in pharmacy in Ireland.

He said that since McKesson announced its takeover of United Drug in 2015 there was an "acceptance" among pharmacists that another sale could occur in the future.

There are now just two pharmacy wholesalers in Ireland. Mr Shanahan said that this created a risk to competition.

"There is a genuine concern in pharmacy… as we really only have two mainline wholesalers at this stage and the risk of course is the risk to competition. When you only have two wholesalers, it creates a risk. I'm not saying it's there, but there is a risk."

Mr Shanahan argued that pharmacy wholesaling in Ireland is a "low margin business", adding that because of this and low profits on offer, the sale "tells its own story".

"It's a function of the fact that we're a small country and the pressures that have been placed on the wholesale margin by the HSE. I think there is still an unwillingness to face the fact that Ireland is a small country and that the cost of distribution of medicines is higher because we are a small country."

# Pharmacy Students in Fundraising Appeal

A group of pharmacy students from University College Cork have decided to mark the end of their learning in a very special and unique way.

The students are raising much needed funds, via GoFund Me, for Cork Penny Dinners - a charity which provides fresh meals, food packages and support to those in need.

"As our five years in UCC draw to a close, giving something back to the city would be a good way to say goodbye," they reflected.

Visit www.gofundme.com/f/pharmacy-2021-supports-cork-penny-dinners for more details and to help them with this extremely worthy cause.


The group of pharmacy students from University College Cork who decided to mark the end of their studies in a very unique way

HEALTHREACH

# QUALITY IRISH FOOD SUPPLEMENTS

MADE IN IRELAND

- ✔ Fast Moving – High Demand
- ✔ Premium Ingredients
- ✔ Lowest RRP's
- ✔ 45% Trade Discount
- ✔ Frequent Promotions
- ✔ Made in Ireland


- Peptan® Hydrolysed Collagen Peptides
- Vitamin C for Collagen Formation in the Skin
- Unflavoured and Lemon Flavour

| Collagen | Code | RSP* | Trade Price * | Barcode |
|---|---|---|---|---|
| 120g Powder Lemon | HR304 | €19.95 | €9.66 | 5390862000801 |
| 200g Powder Lemon | HR306 | €28.95 | €14.03 | 5390862000818 |
| 100g Powder Plain | HR307 | €19.95 | €9.66 | 5390862000825 |
| 165g Powder Plain | HR308 | €28.95 | €14.03 | 5390862000832 |


- Peptan® Hydrolysed Collagen Peptides
- Glucosamine, Chondroitin and MSM
- Lemon Flavour

| Bone Broth | Code | RSP* | Trade Price * | Barcode |
|---|---|---|---|---|
| 125g Powder Lemon | HR350 | €27.95 | €13.54 | 5390862001020 |
| 235g Powder Lemon | HR355 | €39.95 | €19.36 | 5390862001037 |


- Calcium Carbonate and Citric Acid
- Forms Highly Bioavailable Magnesium Citrate
- Flavoured (Fruit) and Unflavoured

| Magnesium | Code | RSP* | Trade Price * | Barcode |
|---|---|---|---|---|
| 100g Powder Plain | HR300 | €9.95 | €4.82 | 5390862000719 |
| 150g Powder Plain | HR302 | €13.95 | €6.76 | 5390862000726 |
| 150g Powder Fruit | HR303 | €15.95 | €7.73 | 5390862000740 |
| Tablets Lemon (20) | HR315 | €9.95 | €4.82 | 5390862000733 |


- 100% Pure D-Mannose Capsules & Powder
- Urinary Tract Health
- Recommended by Consultant Urologists

| D-Mannose | Code | RSP* | Trade Price * | Barcode |
|---|---|---|---|---|
| 60 Capsules | DM001 | €29.95 | €14.51 | 5390862000702 |
| 15 Capsules | DM002 | €12.95 | €6.28 | 5390862000795 |
| 50g Powder | HR309 | €27.95 | €13.55 | 5390862000788 |

## ORDER NOW sales@wholefoods.ie

## Buy Irish – Support Local

*All RSP's include 13.5% VAT and all Trade Prices exclude 13.5% VAT


Wholefoods Wholesale
Unit 3 Kylemore Industrial Estate
Kileen Road, Dublin 10
Tel No: 01 6262315


Wholefoods
NATURAL FOODS & HEALTHCARE

# Pharmacy Graduations and Celebrations

September marked a memorable month for many within pharmacy, as many students celebrated qualifying whilst others noted an end to pharmacy internships.

Liew Chee Foong with Tomás Conefrey and team at Conefrey's CarePlus Pharmacy

Pre-Reg Pharmacist James McLaughlin

Liew Chee Foong, second year Pre-Registration Pharmacy Intern reflected on his time spent with Tomás Conefrey and team at Conefrey's CarePlus Pharmacy. Currently in his final year with Trinity College Dublin he said, "

"Seventeen months ago, at the beginning of the Covid-19 pandemic in Ireland, I stepped into the pharmacy for the first time to temporarily help out as a frontline healthcare student due to staff shortage. That was my very first hands-on community pharmacy experience where my actions would have a direct impact on patient safety.

"Tomás and the team were always genuinely willing to help and guide the new boy in the house. At that point, I discovered the great potential of the team in the development of my career as a prospective pharmacist.

"Fast forward to having completed my 8-month APPEL (Pharmacy Experiential Learning) placement at Conefrey's CarePlus Pharmacy. Tomas, Jamie and Ling – thank you so much for all your teachings and guidance whilst training me towards becoming a competent pharmacist. Marian, Suzanne & Laura – I really appreciated you showing me the ropes of the retail and managerial aspects of front-of-shop pharmacy. Most importantly, all of you made me feel so much part of the family. The laughter and the craic made my days all the brighter amidst the depressive months of lockdown!

"Even many years down my career later, I will always appreciate and never forget where it all began for me in the first place."

August '21 marked the end of three incredible journeys for Pre-Reg Pharmacist James McLaughlin.

"It began with me finally getting to graduate in person and receive my B.Pharm, after 8 months of deferring so I could give my Mum the Trinity College Dublin experience and show her the fruits of our last 4 years of sacrifice and hard work," he said.

"Next came the end of a challenging but incredibly fulfilling final year internship with McCabes Pharmacy alongside the most supportive colleagues I've ever had the good luck to work alongside.

"And finally, I packed up my booth in the Aviva Stadium Mass Vaccination Center for the last time since joining in early May, marking the beginning of the end for the emergency vaccination program. It has been a massive privilege to work alongside veteran healthcare professionals and future leaders alike as part of "the best team to ever play in the Aviva", and to contribute in the response to this pandemic to the best of my abilities."

Pharmacy Intern Miriam Boland also acknowledged her time spent at McCabes Pharmacy stating, "It was a privilege to complete my final eight month placement with McCabes Pharmacy in Dundrum Town Centre! I couldn't have asked for a better team to work with! I'm more excited than ever to qualify as a pharmacist."

Congratulations to all those who graduated and to those embarking on their final years!

Pharmacy Intern Miriam Boland with her pharmacy team at McCabe's Pharmacy

# INDICATED FOR THE PREVENTION OF PNEUMOCOCCAL PNEUMONIA IN ADULTS[1]

PNEUMOCOCCAL
# VACCINATION
VS
PNEUMOCOCCAL
# PNEUMONIA

The persons depicted are models used for illustrative purposes only.

# Prevenar 13®

Pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed

## Help prevent pneumococcal pneumonia with the proven protection of Prevenar 13[1,2]

**Proven to reduce the risk of community-acquired pneumonia: Results from the Community-Acquired Pneumonia Immunisation Trial in Adults (CAPiTA) – one of the largest vaccine efficacy trials ever conducted in older adults.[2,3]**

**ABBREVIATED PRESCRIBING INFORMATION**

**Prevenar 13* Suspension for Injection**
**Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)**

**Presentation:** Each 0.5ml dose of Prevenar 13 contains 2.2 micrograms of each of the following pneumococcal polysaccharide serotypes: 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F and 4.4 micrograms of pneumococcal polysaccharide serotype 6B. Each pneumococcal polysaccharide is conjugated to $CRM_{197}$ carrier protein and adsorbed on aluminium phosphate. 1 dose (0.5 ml) contains approximately 32 µg $CRM_{197}$carrier protein and 0.125 mg aluminium. **Indications:** Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to 17 years of age. Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥18 years of age and the elderly. **Dosage and Administration:** The immunisation schedules for Prevenar 13 should be based on official recommendations. It is recommended that infants who receive a first dose of Prevenar 13 complete the vaccination course with Prevenar 13. For intramuscular injection. Infants aged 6 weeks-6 months: *Three dose primary series:* The recommended immunisation series consists of four doses, each of 0.5ml. The primary infant series consists of three doses, with the first dose usually given at 2 months of age and with an interval of at least 1 month between doses. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age. *Two dose primary series:* Alternatively, when Prevenar 13 is given as part of a routine infant immunisation programme, a series consisting of three doses, each of 0.5ml, may be given. The first dose may be administered from the age of 2 months, with a second dose 2 months later. The third (booster) dose is recommended between 11 and 15 months of age. Preterm infants (< 37 weeks gestation): In preterm infants, the recommended immunisation series consists of four doses, each of 0.5 ml. The primary infant series consists of three doses, with the first dose given at 2 months of age and with an interval of at least 1 month between doses. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age. Unvaccinated infants and children ≥ 7 months of age: *Infants 7-11 months:* Two doses, each of 0.5 ml, with at least a 1 month interval between doses. A third dose is recommended in the second year of life. *Children aged 12-23 months:* Two doses, each of 0.5 ml, with at least a 2 month interval between doses. *Children and adolescents aged 2-17 years:* one single dose of 0.5 ml. Prevenar 13 vaccine schedule for infants and children previously vaccinated with Prevenar (7-valent) (*Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F): Infants and children who have begun immunisation with Prevenar may switch to Prevenar 13 at any point in the schedule. *Children aged 12-59 months:* Children who are considered completely immunised with Prevenar (7-valent) should receive one dose of 0.5 ml of Prevenar 13 to elicit immune responses to the 6 additional serotypes. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent). *Children and adolescents aged 5-17 years:* One single dose of Prevenar 13 if they have been previously vaccinated with one or more doses of Prevenar. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent). *Adults ≥ 18 years of age and the elderly:* One single dose. The need for revaccination with a subsequent dose of Prevenar 13 has not been established. Regardless of prior pneumococcal vaccination status, if the use of 23 valent polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first. *Special Populations:* Individuals who have underlying conditions predisposing them to invasive pneumococcal disease (such as sickle cell disease or HIV infection) including those previously vaccinated with one or more doses of 23-valent pneumococcal polysaccharide vaccine may receive at least one dose of Prevenar 13. In individuals with an haematopoietic stem cell transplant (HSCT), the recommended immunisation series consists of four doses of Prevenar 13, each of 0.5 ml. The primary series consists of three doses, with the first dose given at 3 to 6 months after HSCT and with an interval of at least 1 month between doses. A fourth (booster) dose is recommended 6 months after the third dose. **Contra-indications:** Hypersensitivity to any component of the vaccine or to diphtheria toxoid. As with other vaccines, the administration of Prevenar 13 should be postponed in subjects suffering from acute, severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination. **Warnings and Precautions:** Do not administer intravascularly. Appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic event. This vaccine should not be given as an intramuscular injection to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, but may be given subcutaneously if the potential benefit clearly outweighs the risks of administration. Prevenar 13 will only protect against *Streptococcus pneumoniae* serotypes included in the vaccine, and will not protect against other microorganisms that cause invasive disease, pneumonia, or otitis media. As with any vaccine, Prevenar 13 may not protect all individuals receiving the vaccine from pneumococcal disease. Individuals with impaired immune responsiveness, whether due to the use of immuno-suppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. Safety and immunogenicity data are available for a limited number of individuals with sickle cell disease, HIV infection, or with an HSCT. Safety and immunogenicity data for Prevenar 13 are not available for individuals in other specific immuno-compromised groups (e.g., malignancy or nephrotic syndrome) and vaccination should be considered on an individual basis. **Infants and children aged 6 weeks to 5 years:** Prevenar 13 does not replace the use of 23-valent pneumococcal polysaccharide vaccine in at risk children ≥ 24 months of age. Children ≥ 24 months of age at high risk, previously immunised with Prevenar 13 should receive 23-valent pneumococcal polysaccharide vaccine whenever recommended. The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≥ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. When Prevenar 13 is administered concomitantly with Infanrix hexa (DTPa-HBV-IPV/Hib), the rates of febrile reactions are similar to those seen with concomitant administration of Prevenar (7-valent) and Infanrix hexa. Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of Prevenar 13 and Infanrixhexa. Antipyretic treatment should be initiated according to local guidelines for children with seizure disorders or with a history of febrile seizures and for all children receiving Prevenar 13 simultaneously with vaccines containing whole cell pertussis. **Adults aged 50 years and older:** When Prevenar 13 was given concomitantly with trivalent inactivated influenza vaccine (TIV), the immune responses to Prevenar 13 were lower compared to when Prevenar 13 was given alone, however, there was no long-term impact on circulating antibody levels. The immune responses to Prevenar 13 were noninferior when Prevenar 13 was given concomitantly with quadrivalent inactivated influenza vaccine (QIV) compared to when Prevenar 13 was given alone. As with concomitant administration with trivalent vaccines, immune responses to some pneumococcal serotypes were lower when both vaccines were given concomitantly. **Fertility, Pregnancy & Lactation:** There are no data from the use of pneumococcal 13-valent conjugate in pregnant women. It is unknown whether pneumococcal 13-valent conjugate is excreted in human milk. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. **Side Effects:** Analysis of postmarketing reporting rates suggests a potential increased risk ofconvulsions, with or without fever, and HHE when comparing groups which reported use of Prevenar 13 with Infanrix hexa to those which reported use of Prevenar 13 alone. Adverse reactions reported in clinical studies or from the post-marketing experience for all age groups are listed in this section per system organ class,in decreasing order of frequency and seriousness. The frequency is defined as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (≤ 1/10,000), not known (cannot be estimated from available data). **Infants and children aged 6 weeks to 5 years:** Very common (≥ 1/10): Decreased appetite, fever, pyrexia, irritability, any vaccination-site erythema, induration/swelling or pain/tenderness, somnolence, poor quality sleep. Vaccination-site erythema or induration/swelling 2.5cm – 7.0 cm (after the booster dose and in older children [age 2-5 years]. Common (≥ 1/100 to < 1/10): Vomiting, diarrhoea, rash, pyrexia >39 °C, vaccination-site movement impairment (due to pain), vaccination-site erythema or induration/swelling 2.5cm – 7.0cm (after infant series). Uncommon (≥ 1/1,000 to < 1/100): Convulsions (including febrile convulsions), urticaria or urticaria-like rash, vaccination-site erythema, induration/swelling >7.0cm, crying. Rare: Hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, hypotonic-hyporesponsive episode. Not known: Lymphadenopathy (localised to the region of the vaccination site), anaphylactic/anaphylactoid reaction including shock, angioedema, erythema multiforme, vaccination site urticaria, vaccination-site dermatitis, vaccination-site pruritus, flushing. In clinical studies infants vaccinated at 2, 3 and 4 months of age, fever ≥ 38°C was reported at higher rates among infants who received Prevenar (7-valent) concomitantly with Infanrix hexa than in infants receiving Infanrix hexa alone. After a booster dose at 12 and 15 months of age, the rate of fever ≥ 38°C was greater in infants who received Prevenar (7 valent) and Infanrix hexa at the same time compared to infants receiving Infanrix hexa alone. These reactions were mostly moderate (less than or equal to 39°C) and transient. Additional information in special populations: Apnoea in very premature infants (≤ 28 weeks of gestation). **Children and adolescents aged 6 to 17 years of age:** Very common (≥ 1/10): Decreased appetite, irritability, any vaccination-site erythema, induration/swelling or pain/tenderness, somnolence, poor quality sleep, vaccination-site tenderness (including impaired movement). Common (≥ 1/100 to < 1/10): Headaches, vomiting, diarrhoea, rash, urticaria or urticaria-like rash, pyrexia. Additional information in special populations: Children and adolescents with sickle cell disease, HIV infection or an HSCT transplant have similar frequencies of adverse reactions, except that headaches, vomiting, diarrhoea, pyrexia, fatigue, arthralgia, and myalgia were very common. **Adults ≥18 years of age, and the elderly:** Very common (≥ 1/10): Decreased appetite, headaches, diarrhoea, vomiting,(in adults aged 18 to 49 years), rash, chills; fatigue; vaccination-site erythema; vaccination-site induration/swelling; vaccination-site pain/tenderness (severe vaccination-site pain/tenderness very common in adults aged 18 to 39 years); limitation of arm movement (severe limitation of arm movements very common in adults aged 18 to 39 years), arthralgia; myalgia. Common (≥ 1/100 to < 1/10): Vomiting (in adults aged 50 years and over), pyrexia(very common in adults aged 18 to 29 years). Uncommon (≥ 1/1,000 to < 1/100): Nausea, hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, lymphadenopathy localized to the region of the vaccination site. Additional information in special populations: Adults with HIV infection have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common and nausea common. Adults with an HSCT have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common. **For full prescribing information see the Summary of Product Characteristics. Legal Category:** S1A. **Package Quantities:** Pack of 1 single-dose pre-filled syringe (with separate needle) or pack of 10 single- dose pre-filled syringes. **Marketing Authorisation Numbers:** Single-dose pre-filled syringe (with separate needle) pack of 1: EU/1/09/590/002, single-dose pre-filled syringe pack of 10: EU/1/09/590/003. **Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

**Date of preparation:** 11/2018.

*Trade mark.

**Ref:** PN 11_0 IE.


**References:**
**1.** Prevenar 13 Suspension for Injection Summary of Products Characteristics.
**2.** Bonten M.J.M., Huijts S.M, Bolkenbaas M, et al. Polysaccharide Conjugate Vaccine Against Pneumococcal Pneumonia in Adults. The New England Journal of Medicine. 2015;372:1114-25.
**3.** Pfizer Inc. Press Release Mar 18, 2015.



Date of Preparation: February 2021 | PP-PNA-IRL-0005


Pfizer

# Life Long Learning in Pharmacy

The Life Long Learning in Pharmacy (LLLP) conference series is an international conference series that has been taking place for the past 25 years.

Dr Catriona Bradley, IIOP

LLLP provides an opportunity for national and international colleagues to meet and to discuss their research in the areas of pharmacy education and continued professional development. Pharmacists, educators, researchers, regulators, policy-makers and professional associations from around the world attend the LLLP conferences.

As such, the conference facilitates participant access to high quality educational programs, internationally significant research and development, and world-renowned leaders in the field. LLLP conferences have been convened around the world.

The last event was held in Brisbane in 2018, at which, Dr Catriona Bradley was delighted to announce that Ireland and RCSI were selected as the hosts for 2020 – which became 2021, then 2021 Virtual.

The theme for this conference was 'The Journey of Learning'. This theme represents the experience that we all undertake as we engage in education and adapt to the continuously evolving modern workplace.

Subthemes that were explored through discussion and presentation of research at the event were; - Preparing for the Journey,

- Planning the Route – the stages of our learning journey,
- Provisions and Companions – things that help us in our journey,
- Destinations – where are we going?

The rescheduled event ran from Sunday June 27, to Wednesday June 30. Over 250 delegates registered to attend from across 13 different countries.

There were six keynote events spread over four days: one session for each of the four speakers, and a panel discussion at the beginning and the end of the conference to frame the journey.

- Zubin Austin: Professor and Koffler Chair in Management at the Leslie Dan Faculty of Pharmacy and the Institute for Health Policy, Management, and Evaluation - Faculty of Medicine at the University of Toronto. Zubin discussed Flow, and the Psychology of Engagement and how this could be worked into programme design.
- Mairéad Nic Giolla Mhichíl: Associate Professor and Senior Research Fellow, with the National Institute of Digital Learning in Dublin City University. Mairéad's chosen topic was the Power of the Network in Lifelong Learning.
- Mary E Collins: Senior Executive Development Specialist with RCSI Institute of Leadership. The title of Mary's keynote was 'Mind the Gap' – engaging multigenerational learners in Pharmacy'.
- Alison Strath: interim Chief Pharmaceutical Officer in the Pharmacy and Medicines Division of the Scottish Government Health Directorates

As the final speaker, Alison used her keynote to bring together themes from the previous keynotes, with a focus on the 'Destination' and the importance of interprofessional supports and networks as we navigate a future where medicines and patient treatments are changing.

During the conference there were 23 interactive workshops, as well as over 50 poster presentations, and 90 short oral presentations. To facilitate the wide range of time zones and to maintain and encourage the characteristic spirit of engagement and collaboration of previous LLLPs, the short oral presentations were recorded in advance of the conference for review by delegates at a time of their choosing. Live conference sessions were also recorded for playback.

Overall, the transition to a virtual event was a success. Delegates commended the accessibility of the online platform, and many remarked on the flexibility afforded by an online event. Delegates logged on during the course of their day and in the evening. Despite the challenges posed by an international event, for example time-zones, attendance throughout the event days was high. The high attendance and enthusiastic engagement of our delegates was noted by our online conference providers, who had not seen such levels in many of the other events they had run during the year.

The Life Long Learning in Pharmacy conferences have a loyal following due to the diverse topics and research presented. Dr Bradley and RCSI were honoured to be able to uphold this tradition. Pivoting the event to the virtual medium presented the opportunity to highlight innovative research carried out during the COVID-19 pandemic, by Irish and international researchers. To mitigate for 'Zoom fatigue', the conference programme was varied.

Each morning a group of 60 presenters came together to deliver a one minute summary of their research and encourage the other attendees to engage with their work. There were three very enjoyable social events; a virtual tour of Howth in Dublin, a sequinned spectacular murder mystery event, and a speed dating style World Café networking event.

We would like to acknowledge the contribution of our event sponsors, without whom the switch to virtual would not have been possible.

Sponsors that attended the event included; Monash University, the Royal College of Surgeons in Ireland, Pfizer, The Pharmaceutical Society of New Zealand, Australian Pharmacy Council, Irish Pharmacy Union Academy, Clarity Locums, Hibernian Healthcare, Yakult and the Accreditation Council for Pharmacy Education.

The conference content, including all keynotes and workshops, is available to conference registrants, online for review until the end of 2021.

**Next Event**

The next Life Long Learning in Pharmacy conference will take place in Denver, Colorado, USA from 2-5 July 2023. The conference host convenor is Dr Jodie Malhotra, Director of Practitioner and International Development, Associate Professor, University of Colorado, Skaggs School of Pharmacy and Pharmaceutical Sciences.

The theme for LLLP2023 is 'Blazing New Trails', and will focus on 'climbing the mountain of learning together, simultaneously blazing new trails for our profession and successors'.

The subthemes are

- BASE CAMP – Teaching and Learning Essentials
- ELEVATION – Gaining Ground Through Training
- SUMMIT – Transfer of Learning Through Practice ]
- CARABINEERS, CLIPS & CAIRNS – Tools of the Climb.

Further information on the 2023 conference can be found at lllpharm2023.com

LIFE LONG LEARNING IN PHARMACY 2021
13TH INTERNATIONAL CONFERENCE
THE JOURNEY OF LEARNING
27 - 30 JUNE, DUBLIN, IRELAND

## Alternative Testing Uncovered

A study conducted by RCSI has demonstrated that a PCR test using saliva to test for Covid-19 is almost as accurate as the standard nose and throat swab.

The saliva screening represents a less invasive alternative to the nasal/throat swab and could enable greater capacity for, and uptake of, frequent testing of people who require regular screening.

Professor Steve Kerrigan, the joint lead author of the study and Deputy Head of RCSI's School of Pharmacy and Biomolecular Sciences said,

"The saliva sample to test for Covid-19 can be easily collected by the person themselves so has the potential to increase compliance with screening, particularly for those who require frequent repeated testing. As the saliva test does not require a healthcare professional to conduct it, this method also reduces the risk of infection for test centre staff associated with conducting the nasal/throat swabbing."

The research, carried out in Ireland by RCSI University of Medicine and Health Sciences has been approved by an international panel of peer-reviewers.

The study evaluated the performance of the established "gold standard" nasal/throat swabbing and the more recently developed SalivaDirect approach that tests for Covid-19 in saliva specimens.

The study collected nasal/throat swabs and saliva samples from a cohort of over 300 symptomatic and asymptomatic participants between November 2020 and March 2021. The participants included asymptomatic RCSI students who participated in the study as part of the routine Covid-19 screening programme at the university, and patients admitted to Beaumont Hospital with Covid-19 related respiratory symptoms.

The results revealed that 94% of the positive nose/throat samples also tested positive on the saliva test. 96% of those that tested negative on the nose/throat swab also tested negative on the saliva test.

## Search to find The People's Pharmacist Continues

Nominations have been flooding in to IPN offices as we were going to press with this October issue; as members of the public were keen to acknowledge their appreciation of their local pharmacist.


The search is on to find the People's Pharmacist 2021

In every corner of Ireland, whilst the Covid-19 pandemic closed GP surgeries and hospital capacity overflowed, pharmacists stepped up.

Pharmacy doors remained firmly open during an unprecedented challenging time. Indeed, many patients turned to their community pharmacist for consultations for more serious conditions which are usually dealt with by GPs.

Irish Pharmacy News announced the launch of the People's Pharmacist for 2021, in association with Panadol; last month.

We also launched our specially commissioned video, which went live across all social media platforms.

**The People's Pharmacist Award seeks nominations from across the country**, giving patients the opportunity to recognise and salute their local pharmacist.

Through this Award, we are enabling the public to have a voice in recognising the unwavering support and spirit that makes pharmacists the backbone of our health service in every community across Ireland.

Six finalists will be shortlisted from all nominations received, showcasing the leading stories of compassion and dedication which go above and beyond.

A nation-wide voting process takes place to find The People's Pharmacist 2021 recognising the bravery, hard work and sacrifice pharmacists have made since during the Covid pandemic since March 2020.

***Next months issue of Irish Pharmacy News will showcase the six shortlisted finalists. Don't miss it!***

## Birth Cohort Testing for Hepatitis C

The Health Information and Quality Authority (HIQA) has published a Health Technology Assessment (HTA) recommending the introduction of once-off testing for the Hepatitis C virus (HCV) to people in Ireland born between 1965 and 1985.

HIQA has advised the Minister for Health that implementation of a birth cohort testing programme would be cost-effective and help Ireland achieve its HCV elimination goals. Following a public consultation, the HTA of birth cohort testing for hepatitis C was approved by the Board of HIQA and has been submitted to the Minister for Health for his consideration.

In Ireland, the prevalence of HCV infection is highest amongst those born between 1965 and 1985. Of the 1.5 million people in this cohort, it is estimated that one in every 100 may have chronic HCV infection. HIQA concluded that offering testing to this group would represent good value for money, but that due to the number of individuals involved, testing would have significant upfront costs. HIQA noted that an initial pilot programme would be beneficial to confirm the prevalence estimates and to address issues concerning the feasibility of the programme before rolling it out nationally.

Dr Máirín Ryan, HIQA's Deputy CEO and Director of Health Technology Assessment, said: "Chronic HCV infection is frequently called the 'silent disease', as many people do not have symptoms and don't realise that they are infected. However, the damage it does is not silent. If left untreated, chronic HCV infection can cause severe damage to the liver and other organs. For example, 128 liver transplants completed in Ireland between 2005 and 2018 were due to HCV."

Dr Ryan continued "From reviewing the evidence, we found that the tests available to diagnose chronic HCV infection are highly accurate. Furthermore, the treatments are safe and effective, with over 95% of people treated being cured of their infection."

# Ireland's Health 'Disconnect'

Ireland lags significantly behind on the delivery of personalised healthcare and was found to display a sharp disconnect between policy and implementation of this form of care. That's according to the FutureProofing Personalised Health Index which ranked Ireland as 19th out of 34 other countries. The Irish public's willingness to share data for medical research and care improvements was found to be low with a score of 4 out of 10.


Dr Nina Byrnes and Mary Maguire, Personalised Healthcare Lead, Roche Products (Ireland) Ltd. at the launch of the FutureProofing Personalised Health Index

A panel of Irish healthcare and policy experts was brought together by Roche Ireland to interrogate the Index findings and develop a report with their recommendations for improving Ireland's approach to personalised healthcare. The experts ultimately found that the deficiencies are due to a lack of infrastructure and delays in implementing data sharing policies, meaning Ireland is losing out on opportunities in research, clinical trials and advancements in genomic testing – to the detriment of patients and the Irish healthcare system. Ireland ranked 22nd out of 34 countries for 'Health Services' which includes the planning, organisation and delivery of services that will drive personalised healthcare.

Commenting on the launch of the report, panel member Dr Nina Byrnes, GP, Medical Director Generation Health Medical Clinics, Media Medical Expert said, "The Index revealed significant scope for improvement in Ireland before fully integrated implementation of personalised healthcare can be achieved here. Other countries were found to be far ahead in terms of sharing medical data seamlessly across their health systems and embedding this data in research to further benefit patients and citizens overall. This is something we in Ireland need to prioritise."

The experts found that while Ireland ranked below average across most of the Index measures, there were areas where advancements and improvements have been made since the Index data was collated, most recently due to the Covid-19 pandemic. Specifically, the use of telemedicine has grown exponentially out of necessity since the beginning of the public health crisis, while the introduction of electronic prescriptions has proved hugely beneficial and efficient for medical practitioners, pharmacists and patients alike. Additionally, the panelists agreed that the pandemic may have made the wider public more aware of the merits of clinical research and thus more willing to share their health data.

The FutureProofing Personalised Health Index report outlines the following recommendations for Ireland to address the deficiencies highlighted by the Index and improve its approach to personalised healthcare:

1. The roll out of the national electronic health record (EHR) system is pivotal; it will enable an efficient healthcare delivery system and pave the way for digital health
2. Significant investment will be required, however Sláintecare, the cross-party plan for the future of healthcare, is the most suitable form of delivery of personalised care and could provide necessary funding for the upgrading of data and IT systems
3. The development of an Interdepartmental strategy, aligning academia, medical schools, clinical research and primary/secondary/tertiary care towards the common goal of enabling personalised healthcare could overcome bureaucracy and put the patient first
4. A formalised national policy for genomic testing, as well as an appropriately funded genome resource. This will maximise the benefits of pre-existing and forthcoming targeted therapies and enable the use of data in ground-breaking clinical research
5. A coherent and extensive public awareness campaign to educate the broader public on the value of sharing data for the betterment of medical care and clinical research.

# New Pharmacy App Launched

A new pharmacy app platform went live in the first Irish pharmacies in September, marking a new option for Irish pharmacies looking to future-proof their businesses.

The PharmacyConnect platform offers Apple and Android apps for pharmacy customers, built around a common framework that optimises the user experience for both the customer and the pharmacy.

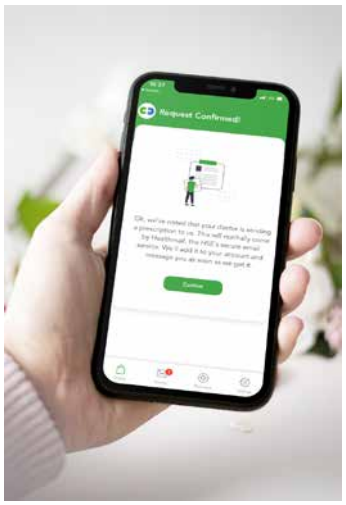
Commencing on the launch of the platform, founder Cormac McKenna said, "We are very pleased to get the first Irish pharmacies on board with the platform and to get their apps into the hands of their customers. The early feedback has been phenomenal and we can already see that the platform will be a key tool in helping pharmacies drive efficiencies and give them a digital experience for their pharmacy that they have come to expect from other industries."

The app is offered in white-labeled versions for pharmacies, meaning that each pharmacy's own brand is used throughout the customer experience and the pharmacy has its own app store presence.

A key feature is a migration tool for Healthmail that allows easy transfer of prescriptions into the hands of customers, thus allowing the pharmacy to be proactive when a prescription arrives and avoiding unnecessary phone calls and emails.

The November issue of Irish Pharmacy News will carry a more in-depth report in this latest new pharmacy offering.

Visit www.pharmacyconnect.ie for more details.




# CLEARLY...

...different skin has different needs.

100% IRISH OWNED

Citrine
Healthcare

**Protect the skin you're in**

www.citrinehealthcare.com

CIT-POS-002B

# Keeping a Finger on the Pharmacy Pulse

Pharmacy Pulse is an analysis of the key trends in the Irish Community Pharmacy sector, prepared by Fitzgerald Power on a quarterly basis. Here we take a closer look at the key findings presented.

## Covid Vaccinations

At the end of June, as the incidence of the Delta variant increased in the population, pharmacists were allowed to administer the J&J vaccine to younger age groups to speed along the vaccine rollout. Pharmacists reported a huge demand for the vaccine, but noted significant supply issues.

## Merger

Haven Pharmacy and totalhealth Pharmacy have agreed to merge, following the approval of members. Haven currently has 49 pharmacies and totalhealth 78 throughout Ireland. The merger will enable the combined entity, which will trade as CommCare Pharma, to manage a supply chain value in the order of €200m per annum. Fitzgerald Power advised on the deal.

## Chemist Warehouse

Chemist Warehouse, Australia's biggest pharmacy chain, has signed a 10-year lease on the former Hickey's Home Focus store on Henry Street in Dublin. It represents one of the first significant new lettings in a year when retail has been blighted by Covid uncertainty. The group has previously agreed a deal on another location in the capital and has plans for more outlets across the country.

## Consolidation

There was notable transaction activity amongst large corporate groups in Q2 2021 with Boots, McCauley's and Uniphar all completing deals. Of these transactions Boots is potentially the most noteworthy. Their acquisition of Butler's Medical Hall in Wicklow Town is the group's first acquisition for 10 years, and marks a change in direction from the previous strategy of opening greenfield units.

## Vaccinations

As of Wednesday 30th June, 4.17million vaccine doses had been administered in Ireland, meaning 63.2% of the adult population had received at least a first dose. This means that 3.2million doses were administered in Q2, which is a significant increase from the first quarter figure of 932,234. The government aims to have a vaccine available for everyone who wants one by the end of the summer.

# Revenue Pulse

## Turnover

Retail Excellence reports an increase of 13.39% in total sales value in Q2 2021 versus the same period last year.

| Value of Sales: Retail Excellence | 13.39% ↑ |
|---|---|

SOURCE: RETAIL EXCELLENCE

The volume of pharmaceutical, medical and cosmetic sales as measured by the CSO, increased by 20% in June 2021 against the same period last year.

| Volume of Sales: CSO | 20% ↑ |
|---|---|

SOURCE: CSO

## Unit Trends

According to HMR Ireland research, the Irish prescription market grew by 8.71% in units compared to the same period last year. Retail Excellence reported dispensary volume growth of 5.51% in Q2 2021 versus Q2 2020.

| Unit Growth: HMR Ireland | 8.71% ↑ |
|---|---|

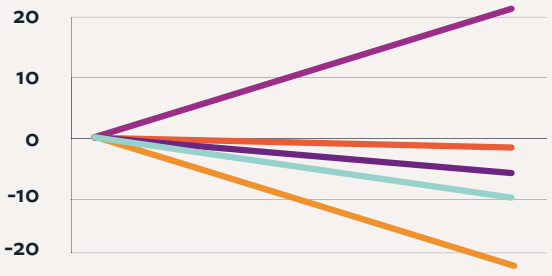
SOURCE: HMR IRELAND

## Footfall Mobililty

Compared to the previous period in 2020, mobility was down 10% in retail and recreation.

The largest decrease was seen in Dublin where mobility declined 23%, whereas the biggest increase was in Kerry at 22%. Mobility declined 1% in Cork and 6% in Limerick over the period.

### Changes in footfall Mobility




Overall -10% Limerick -6% Cork -1%

Kerry 22%
Biggest positive movement

Dublin -23%
Biggest negative movement

SOURCE: GOOGLE MOBILITY

## OTC Tracker

IQVIA data shows the largest growth in OTC sales was in the VMS & tonics category this quarter, whereas the biggest decline was in cough, cold and other respiratory medications. IQVIA report that the OTC market in Ireland contracted by 3% in value and 10% in volume in the year to June 2021 versus the year to June 2020.

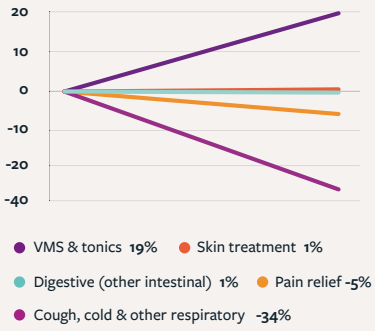
| Value: €421.9m | 3% ↓ |
|---|---|

SOURCE: IQVIA OIRMTH MAT 6/2021

| Volume: €44.3m | 10% ↓ |
|---|---|

SOURCE: IQVIA OIRMTH MAT 6/2021

### Top OTC Classes by Growth




VMS & tonics 19% Skin treatment 1%
Digestive (other intestinal) 1% Pain relief -5%
Cough, cold & other respiratory -34%

SOURCE: IQVIA OIRMTH MAT 6/2021

## Market Pulse

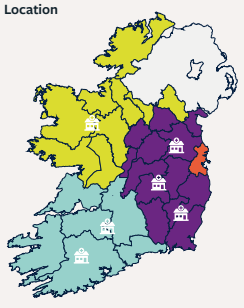
It was another strong quarter for sales, with Fitzgerald Power estimating that six transactions completed in the 2nd Quarter of 2021. Although this is lower than the 15 transactions noted in Q1, it suggests strong consistent growth in the market, particularly when the Cara deal (13 units) is excluded from the Q1 data. A corporate group (Boots, McCauley's and Uniphar) was the purchaser in three of the six transactions recorded in Q2.

### New Openings and Closures

| | |
|---|---|
| New Openings between 1st January – 1st June 2021 | 5 |
| Closures between 1st January – 1st June 2021 | 3 |
| **Net Openings between 1st January – 1st June 2021** | **2** |

SOURCE: PSI

### Completed Deals in Q2 by Geographical Location

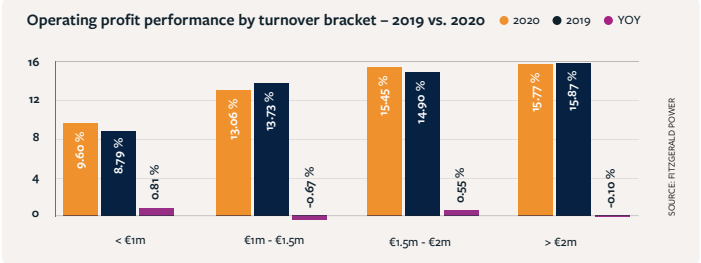


Dublin 0 Ulster/Connacht 1
Munster 2 Leinster 3

SOURCE: FITZGERALD POWER

## Performance Pulse

Overhead spend and operating profit margins remained relatively flat in 2020 with pharmacies in the < €1m and €1m - €1.5m range showing the greatest variance.



# United Drug supports the COVID-19 vaccine rollout

In 2020, United Drug, was chosen by the Irish Government to be the sole distributor of COVID-19 vaccines.

Catherine Cummins, Operations Quality Director, United Drug

As Ireland's leading pharmaceutical distribution company, United Drug rose to the challenge of scaling and adapting its already robust network in a very short timescale to account for the greatest medical challenge in the history of the State and have been responsible for supplying each and every COVID-19 vaccine to vaccination centres, Nursing Homes, Hospitals, GPs, and pharmacies across the country since the beginning of the vaccine roll-out in December 2020.

The company has been supporting public immunization programs since 2007 and is highly experienced in the management of vaccines however, in this instance, it was necessary to further enhance the state of art logistics infrastructure to accommodate the COVID-19 vaccine candidates, including the storage of ultra-low (-70 deg) temperature vaccine (Pfizer BioNTech) and other vaccines which are stored under Freezer (-20deg) temperature (Moderna and Janssen) in addition to Astra Zeneca, which is stored refrigerated (+2 to +8deg).


United Drug's national cold chain service, in collaboration with the HSE, vaccinating Ireland since 2007

> "Our experience and expertise ensured that we were well-placed to receive, store and supply the vaccines assuring the right quality, maintaining traceability and delivering on-time and in-full"

Dedicated members of the United Drug warehouse team in front of the new cold chain fridge storage facility

While the vaccine rollout started slowly due to initial supply constraints, as of the end of August, 2021, Ireland boasts one of the highest vaccinated population percentages in the world.

The teams at United Drug, are very proud of the part they have played in the COVID-19 vaccine roll-out. Operations, Quality, Distribution and Customer Services teams have all worked around the clock to make sure that vaccines were distributed in a safe and timely manner.

They are grateful for the strong collaboration with the many stakeholders involved in the successful implementation of this campaign. It has required a United effort to get over 6.6 million doses into the arms of the Irish population to help to bring a bit of normalcy to our daily lives.

Catherine Cummins, Operations Quality Director with United Drug told Irish Pharmacy News, "The COVID-19 Vaccine roll-out has been an immense challenge for United Drug requiring dedication and agility.

"Our teams have worked tirelessly to adapt to each request and have built a very high standard for Ireland in the Distribution of the vaccines." She adds, "We were challenged with implementing multiple processes within very short windows throughout the past 10 months to ensure that we met the requirement of each vaccine for the HSE and the HPRA; Our experience and expertise ensured that we were well-placed to receive, store and supply the vaccines assuring the right quality, maintaining traceability and delivering on-time and in-full."

The role United Drug plays in the COVID-19 vaccine rollout isn't over yet with the potential for booster activity coinciding with the roll out of the annual flu jab.

United Drug undoubtedly has the expertise and infrastructure to be ready for future requirements on vaccines and other medications, wherever and whenever they are needed. Pharmacies will continue to provide a critical role in the community as de facto primary care centres. This has been evidenced by their involvement in administering COVID vaccines.

They have shown great commitment to community health by taking on the responsibility of providing jabs to hundreds of thousands of people at short notice. They are an ongoing, precious resource that can provide many primary care requirements, including vaccines, and are free, quick, and readily available.

Ostomy & Urology Care
UnitedDrug Retail Solutions

UnitedDrug Wholesale

# Ireland's No. 1 Provider of Ostomy Products & Services

**Customer Care**
Over 20,000 calls handled annually from our customer care team.

**Complimentary Cutting Service**
Cutting up to 10,000 bags per week.

**Training Partnership**
Ostomy Excellence – we provide a complimentary education programme.

**Complimentary wipes and bags**
For Pharmacists to offer their patients.

**Expanding Range**
We continue to expand our range as Ireland's leading stockist for Ostomy & Urology products.

Contact our Ostomy Care team for further information

A McKesson Company

Telephone: 01 463 2300

# LloydsPharmacy: Leading the Way for Pharmacy Colleagues

Irish Pharmacy News recently took a closer look behind the scenes at LloydsPharmacy, Ireland's leading pharmacy chain to uncover what it is that sets them apart and how the company's strategic focus is giving staff greater choice and flexibility.

LloydsPharmacy, Ireland's leading pharmacy chain, and part of McKesson Ireland, employs over 800 colleagues across 89 Pharmacies. With Pharmacies located in many communities and counties of Ireland, the Pharmacy teams enjoy the added benefit of being able to choose locations close to where they live and progress their career with a diverse range of opportunities both in Pharmacy and in Support Office.

United by shared values and principles, the talented and successful teams strive to achieve the Vision of "improving care in every setting" and delivering on the Mission to "Make better Care Possible."

LloydsPharmacy was recently acknowledged for Excellence in Customer Service with the achievement of The Retail Excellence award by Chambers Ireland and InBusiness, for the second time in three years.

This award acknowledges the team's relentless dedication and commitment, delivering excellent customer service and patient care throughout communities in Ireland.

So, what is driving this excellence?

**A Focus on People**

Engaged teams are crucial for a sustainable and successful working environment. One example of how LloydsPharmacy acknowledge and recognise the successes and achievements of the colleagues is through the Employee Recognition Awards.

Happy employees make happy customers.

In April of this year, many of the LloydsPharmacy teams and individuals received awards including LloydsPharmacy Tonlegee RD for "Team of the Year" award, Aylesbury Team for being Customer First, Mary Fitzpatrick from Grove Island Limerick for demonstrating Development Initiatives, Amanda Cooney Category Buyer for being Respectful and IT and Operations for Executing the roll out of the new Dispensary system.

**Training and Development**

Continuous investment in People remains a key driver for success at LloydsPharmacy with over 15,000 annual hours committed every year for ongoing training and development of the colleagues. This ensures the teams have the knowledge, expertise and skills to inspire, grow and develop and provide excellent customer service and best in class patient care.

Front of shop colleagues and Store Managers benefit from a wide spectrum of training including the Management Development programme, Skin Academy, First Aid to Pain Advisor courses.

**Professional Development for Pharmacists**

As part of the professional development of Pharmacists, the teams have been able to attend training and webinars from a range of professional experts in the past year including Dr Niall Colwell, Consultant Cardiologist on Atrial Fibrillation, Sarah Magner on IVF treatment and support, Regina Donnellan RGN on Wound management and dressings, Sepsis Awareness from Joe Hughes, Mental Health Awareness from Stephen McBride at Aware, and Covid-19 and Immunology insights by Professor Luke O'Neill.

**Patient care and support through services**

With the goal of improving patient lives and quality of healthcare, there is a focus on providing a range of services across the Pharmacies. This includes the administering of Flu vaccines, Covid-19 vaccines, Antigen testing, as well as Blood Pressure BMI monitoring, and smoking cessation programmes. Pharmacy teams are encouraged to come up with new ideas, put themselves forward for delivering new services and championing the roll out of patient centric initiatives.

**Strong and Diverse Support**

The Pharmacy teams have the added benefit of strong and diverse support office teams who drive strategy, provide guidance on processes and innovate. This includes the Superintendent Pharmacist and Clinical Governance team, HR, Sales & Operations, Procurement, Marketing, Finance and IT.

The LloydsPharmacy management lead by contributing to a supportive and inclusive work environment where everyone feels connected and engaged and where it is safe to confront facts, take risks, and try out new ideas.

**Want to work for LloydsPharmacy?** ***Are you Looking to progress your Pharmacy career with a progressive and dynamic Pharmacy Chain, with attractive rates, flexible contracts, bonus options and more?***

***There are currently openings for Supervising Pharmacists, Support Pharmacists, OTC colleagues and Beauty Advisors in some Pharmacies.***

***See LloydsPharmacy.ie/pages/careers for more information on open roles.***

***Contact Gary Cardiff on Mobile 0860442927 or by email at gary.cardiff@lloydspharmacy.ie to apply for any of the roles or to get more information on future opportunities.***

# Let's hear from some of the colleagues working in LloydsPharmacy

## Meet Rebecca Barry, Supervising Pharmacist

*We talk to Rebecca Barry, Supervising Pharmacist and Dispensary Manager at LloydsPharmacy, Castletroy to learn more about her job and experience in working as part of the team for the last 13 years.*

**What's your role?** I'm the supervising pharmacist, dispensary manager.

**What do you like about working in LloydsPharmacy?** I LOVE my job. We have a big vibrant team, not only in the store itself, but in the wider community of LloydsPharmacy Ireland. It's a very supportive environment, we help each other out between stores, and I have peers to lean on and get their take on things as they arise.

My workday flies by and I learn so many new things every single day.

**Why choose LloydsPharmacy over other pharmacies?** We're one of the largest pharmacy chains in Ireland and yet we have a big emphasis on being very much rooted in the community. We passionately believe in putting the customer first and in engaging and getting to know our patients. There are great opportunities within LloydsPharmacy to be involved in work outside of the core pharmacist role, as well as career growth.

**What do you love about being a Pharmacist in LloydsPharmacy?** LloydsPharmacy have been very supportive in enabling me to do work with pharmacy organisations outside of LloydsPharmacy such as with the IPU and the IIOP. I've also been encouraged to be involved in pilots both nationally and within LloydsPharmacy.

There's a big, diverse team of pharmacists working in LloydsPharmacy from lots of different backgrounds. Meeting up for training days etc are always great and we help each other out a lot, there's always someone to help if you're stuck for a day off for example.

**What has LloydsPharmacy changed about you as an employee?** LloydsPharmacy has exposed me to wider roles such as my involvement in marketing and media campaigns with them.

**What excites you about your role?** I am absolutely NEVER bored in work! I'm involved in the best and worst parts of people's lives, from being the first person to be told about a pregnancy (on occasion even before the prospective Daddy!), to a cancer diagnosis, palliative care and the loss of a loved one.

## Meet Stephen Forsythe

*We talk to Stephen Forsythe, Supervising Pharmacist at LloydsPharmacy to learn more about his experiences as a member of the team for the last 15 years.*

**How long have you worked in LloydsPharmacy?** 15 years

**What's your role?** Supervising Pharmacist at LloydsPharmacy Agnes Road

**What do you like about working in LloydsPharmacy?** The people, the colleagues I work with are great.

**Why did you choose Pharmacy?** Pharmacy is a vocation which offers a diverse range of opportunities. I choose the community pharmacy path as I enjoy helping and interacting with patients. I like being around people.

**Why choose LloydsPharmacy over other pharmacies?** I sort of fell into working for LloydsPharmacy. I was a locum and the position came up and it suited me to have regular work and a stable income, and hey 15 years later I'm still with LloydsPharmacy.

**What areas of Pharmacy interest you?** The area that is most interesting to me is counselling of patients. I feel I can impact the health and safety of the patient strongly by engaging with them and discussing their medication and their medical conditions. Sometimes the feedback I get from the patient can allow me to address how I can treat other patients with a similar condition. So, talking to patients can teach you a lot.

**What do you love about being a Pharmacist in LloydsPharmacy?** Working for LloydsPharmacy encompasses so many different parts of the business, everything from cosmetic and skin care, to vitamins, OTC and obviously prescriptions. You can learn so much by surrounding yourself with a company that basically has experts in all these fields. You have opportunities to learn on the job and from pharmacy courses organised by leading manufactures via LloydsPharmacy support colleagues.

**What has LloydsPharmacy changed about you as an employee?** You meet colleagues with different life experiences, and different ways of approaching problems, or accessing information. When I meet new colleagues I take that opportunity to learn and, from that, grow.

**What excites you about your role?** I guess with COVID-19 lots of new innovating measures are taking place especially online. I am looking forward to seeing how this area progress's over the coming years.

## Meet Eddie Maguire, Supervising Pharmacist at Stoneybatter

**How long have you worked in LloydsPharmacy?** I joined in 2006. I am originally from Armagh but was happy to move to take up the role with LloydsPharmacy after I graduated from QUB.

**What's your role?** Supervising Pharmacist at Stoneybatter

**Why choose LloydsPharmacy over other pharmacies?** I attended a careers fair and met some of the LloydsPharmacy recruitment team. It was the size of the company and the support from HR to help me relocate that appealed to me most.

**What do you love about being a Pharmacist in LloydsPharmacy?** I love the variety of the role. I have progressed from Relief Pharmacist to Supervising Pharmacist and have contributed to several special operational projects.

**What has LloydsPharmacy changed about you as an employee?** It's a large company and I have been able to transfer to a Pharmacy close to where I live. The Pharmacy opening hours suit me as I can dedicate time to being with my family in the evenings and at the weekend as that's important to me.


# Join the Experts

At Ireland's Leading Pharmacy Chain

LloydsPharmacy

# Current Vacancies

## Meet Erika Van Der Spuy Pharmacy Technician at Artane SC

*We talk Erika Van Der Spuy, Technician at LloydsPharmacy to learn more about her job and experience in working as part of the team.*

**What's your role?** Technician at LloydsPharmacy Artane SC Dublin

**Why choose LloydsPharmacy over other pharmacies?** I am originally from South Africa. I was lucky to have friends who helped me find open roles with LloydsPharmacy. Whilst it might seem daunting to relocate from South Africa to Ireland it really wasn't difficult. I received such great support.

**What do you like about working in LloydsPharmacy?** Apart from the great job, I find the teams are so encouraging and supportive. They have been with me at every step of the way helping me settle here in Ireland.

**What areas of Pharmacy interest you?** I love my job and am hoping to progress my career with LloydsPharmacy. I am currently studying to become a Pharmacist

**What do you love about being a Pharmacist Technician in LloydsPharmacy?** It's a great place to do my training. The People are so warm and friendly.

| POSITION | CONTRACT TYPE | COUNTY | LOCATION |
|---|---|---|---|
| Supervising Pharmacist Manager | Permanent | Limerick | William St |
| Supervising Pharmacist | Permanent | Carlow | Tullow St |
| Supervising Pharmacist | Permanent | Dublin | Rowlagh |
| Supervising Pharmacist | Permanent | Dublin | The Mill SC |
| Supervising Pharmacist | Permanent | Dublin | Blanchardstown SC |
| Supervising Pharmacist | Mat. Leave | Dublin | Raheny |
| Supervising Pharmacist | Mat. Leave | Dublin | Cabra |
| Supervising Pharmacist | Permanent | Dublin | Aylesbury |
| Supervising Pharmacist | Permanent | Sligo | Collooney |
| Supervising Pharmacist | Permanent | Wexford | Wellingtonbridge |
| Support Pharmacist | Permanent | Cork | Hollyhill |
| Support Pharmacist | Permanent | Dublin | The Mill SC |
| Support Pharmacist | Permanent | Dublin | Dun Laoghaire |
| Support Pharmacist | Permanent | Dublin | Artaine |
| Support Pharmacist | Permanent | Dublin | Tonlegee |
| Support Pharmacist | Permanent | Dublin | Drumcondra |
| Support Pharmacist | Permanent | Dublin | Blanchardstown |
| Support Pharmacist | Permanent | Dublin | Rowlagh |
| Support Pharmacist | Permanent | Dublin | Shankill |
| Support Pharmacist | Permanent | Kerry | Fairies Cross |
| Support Pharmacist | Permanent | Portlaoise | Laois SC |
| Relief Pharmacists | | Various locations | |

United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland, D24 XKE5
**lloydspharmacy.ie**

heLlo

# INDICATED FOR THE PREVENTION OF PNEUMOCOCCAL PNEUMONIA IN ADULTS[1]

## IN ADULTS AGED ≥ 65 YEARS

### With each additional comorbid condition, the risk for pneumococcal pneumonia multiplies compared to healthy adults of the same age[2]

**1 underlying condition**
**2.1x increased risk**

**2 underlying conditions**
**4.2x increased risk**

**≥3 underlying conditions**
**9.2x increased risk**

**These underlying conditions included[2]:**

- Alcoholism
- Asthma
- Chronic cardivascular disease
- Chronic liver disease
- Chronic pulmonary disease
- Current smokers
- Diabetes

# Prevenar 13®

Pneumococcal polysaccharide conjugate vaccine, 13-valent adsorbed

## Help prevent pneumococcal pneumonia with the proven protection of Prevenar 13[1,3]

**Proven to reduce the risk of community-acquired pneumonia: Results from the Community-Acquired Pneumonia Immunisation Trial in Adults (CAPiTA) – one of the largest vaccine efficacy trials ever conducted in older adults.[3,4]**

**ABBREVIATED PRESCRIBING INFORMATION**

**Prevenar 13* Suspension for Injection**

**Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)**

**Presentation:** Each 0.5ml dose of Prevenar 13 contains 2.2 micrograms of each of the following pneumococcal polysaccharide serotypes: 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F and 4.4 micrograms of pneumococcal polysaccharide serotype 6B. Each pneumococcal polysaccharide is conjugated to $CRM_{197}$ carrier protein and adsorbed on aluminium phosphate. 1 dose (0.5 ml) contains approximately 32 µg $CRM_{197}$ carrier protein and 0.125 mg aluminium. **Indications:** Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents from 6 weeks to 17 years of age. Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥18 years of age and the elderly. **Dosage and Administration:** The immunisation schedules for Prevenar 13 should be based on official recommendations. It is recommended that infants who receive a first dose of Prevenar 13 complete the vaccination course with Prevenar 13. For intramuscular injection. Infants aged 6 weeks-6 months: *Three dose primary series:* The recommended immunisation series consists of four doses, each of 0.5ml. The primary infant series consists of three doses, with the first dose usually given at 2 months of age and with an interval of at least 1 month between doses. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age. *Two dose primary series:* Alternatively, when Prevenar 13 is given as part of a routine infant immunisation programme, a series consisting of three doses, each of 0.5ml, may be given. The first dose may be administered from the age of 2 months, with a second dose 2 months later. The third (booster) dose is recommended between 11 and 15 months of age. Preterm infants (< 37 weeks gestation): In preterm infants, the recommended immunisation series consists of four doses, each of 0.5 ml. The primary infant series consists of three doses, with the first dose given at 2 months of age and with an interval of at least 1 month between doses. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age. Unvaccinated infants and children ≥ 7 months of age: *Infants 7-11 months:* Two doses, each of 0.5 ml, with at least a 1 month interval between doses. A third dose is recommended in the second year of life. *Children aged 12-23 months:* Two doses, each of 0.5 ml, with at least a 2 month interval between doses. *Children and adolescents aged 2-17 years:* one single dose of 0.5 ml. Prevenar 13 vaccine schedule for infants and children previously vaccinated with Prevenar (7-valent) (*Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F): Infants and children who have begun immunisation with Prevenar may switch to Prevenar 13 at any point in the schedule. *Children aged 12-59 months:* Children who are considered completely immunised with Prevenar (7-valent) should receive one dose of 0.5 ml of Prevenar 13 to elicit immune responses to the 6 additional serotypes. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent). *Children and adolescents aged 5-17 years:* One single dose of Prevenar 13 if they have been previously vaccinated with one or more doses of Prevenar. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent). *Adults ≥18 years of age and the elderly:* One single dose. The need for revaccination with a subsequent dose of Prevenar 13 has not been established. Regardless of prior pneumococcal vaccination status, if the use of 23 valent polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first. *Special Populations:* Individuals who have underlying conditions predisposing them to invasive pneumococcal disease (such as sickle cell disease or HIV infection) including those previously vaccinated with one or more doses of 23-valent pneumococcal polysaccharide vaccine may receive at least one dose of Prevenar 13. In individuals with an haematopoietic stem cell transplant (HSCT), the recommended immunisation series consists of four doses of Prevenar 13, each of 0.5 ml. The primary series consists of three doses, with the first dose given at 3 to 6 months after HSCT and with an interval of at least 1 month between doses. A fourth (booster) dose is recommended 6 months after the third dose. **Contra-indications:** Hypersensitivity to any component of the vaccine or to diphtheria toxoid. As with other vaccines, the administration of Prevenar 13 should be postponed in subjects suffering from acute, severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination. **Warnings and Precautions:** Do not administer intravascularly. Appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic event. This vaccine should not be given as an intramuscular injection to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, but may be given subcutaneously if the potential benefit clearly outweighs the risks of administration. Prevenar 13 will only protect against *Streptococcus pneumoniae* serotypes included in the vaccine, and will not protect against other microorganisms that cause invasive disease, pneumonia, or otitis media. As with any vaccine, Prevenar 13 may not protect all individuals receiving the vaccine from pneumococcal disease. Individuals with impaired immune responsiveness, whether due to the use of immuno-suppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have reduced antibody response to active immunization. Safety and immunogenicity data are available for a limited number of individuals with sickle cell disease, HIV infection, or with an HSCT. Safety and immunogenicity data for Prevenar 13 are not available for individuals in other specific immuno-compromised groups (e.g., malignancy or nephrotic syndrome) and vaccination should be considered on an individual basis. **Infants and children aged 6 weeks to 5 years:** Prevenar 13 does not replace the use of 23-valent pneumococcal polysaccharide vaccine in at risk children ≥ 24 months of age. Children ≥ 24 months of age at high risk, previously immunised with Prevenar 13 should receive 23-valent pneumococcal polysaccharide vaccine whenever recommended. The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≥ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. When Prevenar 13 is administered concomitantly with Infanrix hexa (DTPa-HBV-IPV/Hib), the rates of febrile reactions are similar to those seen with concomitant administration of Prevenar (7-valent) and Infanrix hexa. Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of Prevenar 13 and Infanrixhexa. Antipyretic treatment should be initiated according to local guidelines for children with seizure disorders or with a history of febrile seizures and for all children receiving Prevenar 13 simultaneously with vaccines containing whole cell pertussis. **Adults aged 50 years and older:** When Prevenar 13 was given concomitantly with trivalent inactivated influenza vaccine (TIV), the immune responses to Prevenar 13 were lower compared to when Prevenar 13 was given alone, however, there was no long-term impact on circulating antibody levels. The immune responses to Prevenar 13 were noninferior when Prevenar 13 was given concomitantly with quadrivalent inactivated influenza vaccine (QIV) compared to when Prevenar 13 was given alone. As with concomitant administration with trivalent vaccines, immune responses to some pneumococcal serotypes were lower when both vaccines were given concomitantly. **Fertility, Pregnancy & Lactation:** There are no data from the use of pneumococcal 13-valent conjugate in pregnant women. It is unknown whether pneumococcal 13-valent conjugate is excreted in human milk. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. **Side Effects:** Analysis of postmarketing reporting rates suggests a potential increased risk ofconvulsions, with or without fever, and HHE when comparing groups which reported use of Prevenar 13 with Infanrix hexa to those which reported use of Prevenar 13 alone. Adverse reactions reported in clinical studies or from the post-marketing experience for all age groups are listed in this section per system organ class,in decreasing order of frequency and seriousness. The frequency is defined as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (≤ 1/10,000), not known (cannot be estimated from available data). **Infants and children aged 6 weeks to 5 years:** Very common (≥ 1/10): Decreased appetite, fever, pyrexia, irritability, any vaccination-site erythema, induration/swelling or pain/tenderness, somnolence, poor quality sleep. Vaccination-site erythema or induration/swelling 2.5cm – 7.0 cm (after the booster dose and in older children [age 2-5 years]. Common (≥ 1/100 to < 1/10): Vomiting, diarrhoea, rash, pyrexia >39 °C, vaccination-site movement impairment (due to pain), vaccination-site erythema or induration/swelling 2.5cm – 7.0cm (after infant series). Uncommon (≥ 1/1,000 to < 1/100): Convulsions (including febrile convulsions), urticaria or urticaria-like rash, vaccination-site erythema, induration/swelling >7.0cm, crying. Rare: Hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, hypotonic-hyporesponsive episode. Not known: Lymphadenopathy (localised to the region of the vaccination site), anaphylactic/anaphylactoid reaction including shock, angioedema, erythema multiforme, vaccination site urticaria, vaccination-site dermatitis, vaccination-site pruritus, flushing. In clinical studies infants vaccinated at 2, 3 and 4 months of age, fever ≥ 38°C was reported at higher rates among infants who received Prevenar (7-valent) concomitantly with Infanrix hexa than in infants receiving Infanrix hexa alone. After a booster dose at 12 and 15 months of age, the rate of fever ≥ 38°C was greater in infants who received Prevenar (7 valent) and Infanrix hexa at the same time compared to infants receiving Infanrix hexa alone. These reactions were mostly moderate (less than or equal to 39°C) and transient. Additional information in special populations: Apnoea in very premature infants (≤ 28 weeks of gestation). **Children and adolescents aged 6 to 17 years of age:** Very common (≥ 1/10): Decreased appetite, irritability, any vaccination-site erythema, induration/swelling or pain/tenderness, somnolence, poor quality sleep, vaccination-site tenderness (including impaired movement). Common (≥ 1/100 to < 1/10): Headaches, vomiting, diarrhoea, rash, urticaria or urticaria-like rash, pyrexia. Additional information in special populations: Children and adolescents with sickle cell disease, HIV infection or an HSCT transplant have similar frequencies of adverse reactions, except that headaches, vomiting, diarrhoea, pyrexia, fatigue, arthralgia, and myalgia were very common. **Adults ≥18 years of age, and the elderly:** Very common (≥ 1/10): Decreased appetite, headaches, diarrhoea, vomiting,(in adults aged 18 to 49 years), rash, chills; fatigue; vaccination-site erythema; vaccination-site induration/swelling; vaccination-site pain/tenderness (severe vaccination-site pain/tenderness very common in adults aged 18 to 39 years); limitation of arm movement (severe limitation of arm movements very common in adults aged 18 to 39 years), arthralgia; myalgia. Common (≥ 1/100 to < 1/10): Vomiting (in adults aged 50 years and over), pyrexia(very common in adults aged 18 to 29 years). Uncommon (≥ 1/1,000 to < 1/100): Nausea, hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, lymphadenopathy localized to the region of the vaccination site. Additional information in special populations: Adults with HIV infection have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common and nausea common. Adults with an HSCT have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common. **For full prescribing information see the Summary of Product Characteristics. Legal Category:** S1A. **Package Quantities:** Pack of 1 single-dose pre-filled syringe (with separate needle) or pack of 10 single- dose pre-filled syringes. **Marketing Authorisation Numbers:** Single-dose pre-filled syringe (with separate needle) pack of 1: EU/1/09/590/002, single-dose pre-filled syringe pack of 10: EU/1/09/590/003. **Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500.

**Date of preparation:** 11/2018.

*Trade mark.

**Ref:** PN 11_0 IE.

**References: 1.** Prevenar 13 Suspension for Injection. Summary of Product Characteristics. **2.** Shea K, Edelsberg J, Weycker D, et al. Rates of Pneumococcal Disease in Adults with Chronic Medical Conditions. Open Forum Infectious Disease. 2014;1-9. **3.** Bonten M.J.M., Huijts S.M, Bolkenbaas M, et al. Polysaccharide Conjugate Vaccine Against Pneumococcal Pneumonia in Adults. The New England Journal of Medicine. 2015;372:1114-25. **4.** Pfizer Inc. Press Release Mar 18, 2015.



Pfizer

# Pharmacy Role in Smoking Cessation

*In order to help people quit smoking, it's important that we understand some of the reasons why people smoke to begin with. It's obviously physiologically addictive but it can be a pleasurable habit. It's often a highly social activity, think of the bustling smoking sections, but also an act that requires one to draw breath over an extended series of seconds, and exhale, slowly and with some sense of control. This, in many ways, is describing a relaxation method, albeit one with negative consequences.*

*Written by Dr Damien Lowry*
*Chartered Senior*
*Counselling Psychologist*

## Prevalence of smoking in Ireland

Ireland has traditionally had high levels of smoking and two primary sources of prevalence estimates exist. One is the HSE 'tracker' survey, done quarterly by phone since 2002, sampling c4,000 responses annually. The other is a Healthy Ireland (HI) survey, which is a face-to-face household survey since 2015, sampling 7,500 people annually. Both surveys indicate a downward trend in smoking prevalence in recent years. In 2005, one-in-four people in the general population smoked, falling year-on-year to 15.4% of society in 2020. Smoking is most prevalent in those aged 18-35 and decreases with increasing age. A disproportionate prevalence has also been noted in disadvantaged socioeconomic groups, with smoking rates among manual labourers being double the rate of skilled professionals. Here are some stark facts in relation to smoking in Ireland.

## Smoking facts:

- 1 in every 2 smokers will die from a tobacco-related disease.
- Smoking takes an estimated 10-15 quality years off your life
- Every cigarette smoked reduces your life by an estimated 5mins 30sec
- Most smokers (83%) regret starting and would not smoke if they could choose again
- Rolling tobacco has increased significantly since 2003 (3% to 30%)
- Smoking is the leading cause of avoidable death.
- Nearly 6,000 people die each year from the effects of smoking and thousands more suffer from smoking-related diseases.

## Government Strategy on Tobacco

The Tobacco-Free Ireland (TFI) Policy document was developed by the Department of Health in 2013. This government strategy (2013 - 2025) has a number of cross-governmental actions which are based on the six national standards of the WHO report on the Global Tobacco Epidemic 2008:

1. Monitoring of tobacco use and prevention policies
2. Protecting people from second-hand smoke
3. Offering help to people who want to quit
4. Warning of the dangers of tobacco
5. Enforcing bans on advertising, promotion and sponsorship
6. Raising taxes on tobacco

This report seeks to de-normalise tobacco within society, reduce initiation rates, assist smokers to quit, protect non-smokers, especially children, from the effects of second-hand smoke, by building a stable policy and legislative framework. The final (sixth) direction results in two-fold benefits: firstly, more revenue is raised for the exchequer, which can offset the cost of providing healthcare for tobacco smoking related conditions; and additional tax increases on cigarettes is also associated with a reduction in smoking numbers.

## Why Stop?

Smoking is a major risk factor for lung disease, premature death and it's an expensive habit. Research from Respiratory Medicine suggests that those with mild-to-moderate chronic obstructive pulmonary disease (COPD), who quit, achieve normalisation of lung function within one year of quitting. Furthermore, the risk of heart attack and stroke declines within one month as does the risk of associated disease. After one year your risk of coronary heart disease drops to half that of a current smoker. There are also additional benefits to quitting, such as, improved taste and smell, increased energy, improved bodily healing and whiter teeth.

## Support

There are myriad resources to help someone quit if they are open to it. Whilst the decision to quit must come from the person themselves motivational interviewing techniques can be a helpful, non-judgemental approach for professionals to use when encouraging a person to consider quitting. To this end, it's helpful to suggest a person anchors their reason to quit in their values ('to be healthy', 'to be around longer for their kids' etc rather than to simply sacrifice a vice). Once a person commits to quitting, there are various resources to avail of, between smoking helplines and online resources. In terms of therapeutics, nicotine replacement therapy is recommended by the HSE whereas e-cigarettes are not, given the lack of long-term data on health outcomes. However, there is a growing opinion that 'vaping' as it has become called, is preferable to smoking itself and so clinical judgement might be useful in helping to steer someone away from an addictive habit well known to cause significant morbidity and mortality, in terms of what actually might help a person to quit.

## Information

For more information and guidance see: https://www2.hse.ie/quit-smoking/

NiQuitin®
Nicotine

# "I quit smoking for her"

*Fergus O'Shea*

## Help smokers quit with an unbeatable combination* from NiQuitin


**NiQuitin Patch**
Ireland's **number one** 24 hour patch**

**NiQuitin Mini**
On the go craving relief

IRE NIQ 2021 19

*Provides significant improvement in quit rate vs patch alone. To verify contact verify@perrigo.com. Stead LF et al. 2012 Nicotine replacement therapy for smoking cessation, Cochrane Library. **Based on sales data. To verify contact verify@perrigo.com

**NiQuitin CLEAR 24 hrs transdermal patches** are indicated for the relief of nicotine withdrawal symptoms including cravings as an aid to smoking cessation. Indicated in adults and adolescents aged 12 years and over. NiQuitin patches should be applied once a day, at the same time each day and preferably soon after waking and worn continuously for 24 hours. Apply a patch to non-hairy clean dry skin surface, a new skin site should be used every day. Therapy should usually begin with NiQuitin 21 mg/24 hrs and reduced according to the following dosing schedule: **Step1:** NiQuitin Clear 21 mg/24 hrs transdermal patches first 6 weeks. **Step 2:** NiQuitin Clear 14 mg/24 hrs transdermal patches next 2 weeks. **Step 3:** NiQuitin Clear 7 mg/24 hrs transdermal patches last 2 weeks. Light smokers (less than 10 cigarettes per day) are recommended to start at Step 2 (14 mg) for 6 weeks and decrease the dose to NiQuitin 7 mg/24 hrs for the final 2 weeks. In some instances (e.g. heavy smokers, those who have relapsed after NRT, or when one NRT product is not enough to control cravings), NiQuitin patches may be used in combination with a nicotine oral format (refer to the package leaflet for dosing guidance). **Contraindications:** Non-smokers, hypersensitivity, children under 12 years and occasional smokers. **Precaution:** Supervise use if hospitalised for MI, severe dysrhythmia or CVA, if haemodynamically unstable. Use with caution in patients with active oesophagitis, oral and pharyngeal inflammation, gastritis, peptic ulcers, GI disturbances, susceptible to angioedema, urticaria, renal/hepatic impairment, hyperthyroidism, diabetes, phaeochromocytoma, seizures & epilepsy. Discontinue if severe persistent skin rash. **Pregnancy and lactation:** Oral formats preferable to patches unless nauseous. Remove patches at bedtime. **Side effects:** *Sleep disorders, abnormal dreams, insomnia, headache, dizziness, nausea, vomiting, application site reactions, nervousness, palpitations, dyspnoea, pharyngitis, cough, dyspepsia, upper abdominal pain, diarrhoea, constipation, dry mouth, sweating, localised pain, urticaria, hypersensitivity, tremor, nervousness, palpitations, tachycardia, contact & allergic dermatitis, photosensitivity, arthralgia, myalgia, asthenia, malaise, influenza-type illness, fatigue, chest or limb pain, pain, seizures and anaphylaxis.* **Legal classification: GSL: PA 1186/18/4, PA 1186/18/5 & PA 1186/18/6. MAH:** Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland. https://www.medicines.ie/medicines/niquitin-clear-7-mg-24-hours-transdermal-patch-33085/patient-info https://www.medicines.ie/medicines/niquitin-clear-14-mg-24-hours-transdermal-patch-33083/patient-info https://www.medicines.ie/medicines/niquitin-clear-21-mg-24-hours-transdermal-patch-33084/patient-info **NiQuitin Mini 1.5mg/4mg Mint Lozenges** are used for the treatment of tobacco dependence by relief of nicotine withdrawal symptoms and cravings. Indicated in adults and adolescents aged 12 years and over. NiQuitin Mini 1.5 mg are suitable for those who smoke 20 cigarettes or less a day. NiQuitin Mini 4 mg are suitable for smokers who smoke more than 20 cigarettes a day. Place a lozenge in the mouth whenever there is an urge to smoke, allow to dissolve completely. Do not chew or swallow whole. In heavy smokers, those who have relapsed after NRT, or when one NRT is not enough to control cravings, NiQuitin Minis may be used in combination with NiQuitin patches (refer to the package leaflet for dosing guidance). **Abrupt cessation:** Use a lozenge whenever there is an urge to smoke, maximum of 15 lozenges a day. Continue for up to 6 weeks, then gradually reduce lozenge use. Gradual cessation Use lozenges whenever there is an urge to smoke in order to reduce the number of cigarettes smoked for up to 6 weeks, followed by abrupt cessation. **Adolescents (12-17 years):** only with advice from a healthcare professional. Should not quit with a combination NRT regimen. **Contraindications:** hypersensitivity to nicotine or any of the excipients, children under the age of 12 years and non-smokers. **Precaution:** Supervised use in dependent smokers with a recent myocardial infarction, unstable or worsening angina pectoris including Prinzmetal's angina, severe cardiac arrhythmias, uncontrolled hypertensions or recent cerebrovascular accident. Use with caution in those with; stable cardiovascular diseases, diabetes mellitus, susceptibility to angioedema & urticaria, renal/hepatic impairment, phaeochromocytoma &uncontrolled hyperthyroidism, GI disease & seizures. **Side effects:** *Nausea, mouth/throat and tongue irritation, irritability, anxiety, sleep disorders, dizziness, headaches, cough, sore throat, vomiting, diarrhoea, GI and oral discomfort, flatulence, hiccups, heartburn, dyspepsia, dry mouth, constipation, ulcerative stomatitis, pharyngitis, nervousness, depression, palpitations, heart rate increased, dyspnoea, rash, angioedema, pruritus, erythema, hyperhidrosis, fatigue, malaise chest pain, anaphylactic reactions, hypersensitivity, tremor, dysgeusia, paresthesia mouth, seizures & epilepsy, dysphagia, eructation, salivary hypersecretion, influenza like illness.* **Legal classification: GSL: PA 1186/18/11 & PA 1186/18/12 MAH:** Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland. https://www.medicines.ie/medicines/niquitin-mini-1-5mg-mint-lozenges-33090/smpc https://www.medicines.ie/medicines/niquitin-mini-4mg-mint-lozenges-33091/smpc

# Ireland leads the Way on Tobacco Cessation Programmes

*As a recognized global leader in tobacco control, Ireland has worked hard to develop comprehensive treatment for tobacco dependence. The country's efforts are underpinned by ambitious goals: it aims to be tobacco free by 2025 with a smoking prevalence equal to or lower than 5%. One of Ireland's keys to success is a rigorous national cessation programme that provides care and support for those struggling with tobacco and nicotine dependence.*

As part of the 2021 World No Tobacco Day campaign "Commit to Quit", the World Health Organisation Europe recently explored Ireland's world-class stop-smoking services, shining a light on the success of countries working to create a tobacco-free world.

"We now have more quitters than smokers in Ireland," says Martina Blake, National Lead of the Health Service Executive (HSE) Tobacco Free Ireland Programme. "Unfortunately, as we know from the Healthy Ireland survey, most smokers try to quit alone and don't use recognized and evidence-based cessation aids. We would like to encourage all smokers to give themselves the best chance of success and use our friendly and supportive services."

It can be hard to quit smoking, but the chances of succeeding are drastically increased with the right support. Smokers are twice as likely to succeed in ending tobacco addiction with the help of tobacco cessation programmes provided by Ireland's HSE, and 4 times more likely with a combination of cessation programmes and medication.

## Comprehensive cessation programmes

Ireland's comprehensive cessation services cover a bespoke range of options for tobacco users who want to quit, from a free quitline and live chat on the quit.ie website to "community quitters" Facebook groups and a free online quit plan. The headline service is the structured behavioural support programme.

Implementing comprehensive cessation programmes is important, but can appear daunting or resource-intensive for some countries. A stepwise approach can be helpful for developing support systems in an affordable manner. Ensuring that everyone in society – particularly the most vulnerable – can access cessation services increases the chance of success and boosts progress towards a tobacco-free future.

## Tailored support

Ireland is tailoring tobacco-cessation support to specific groups, particularly those in disadvantaged communities, whose unique needs are assessed early in the process.

"Those who have a long smoking history, are heavily addicted or have mental health difficulties often need extra and extended support, particularly in line with other factors like unemployment or concurrent addictions," Martina says.

"We are beginning to invest in specific services for pregnant smokers and for those in disadvantaged communities. Extra behavioural support sessions are available for people in these groups and can extend beyond the standard 8 sessions over the 12-month period."

Tobacco advisers for disadvantaged groups are often local peer leaders trained within the community they serve. This improves rates of quitting by increasing engagement and building trust, and places cultural sensitivity at the forefront of the cessation programme.

## Affordable support in the right place

Ensuring that smoking cessation services are free to everyone and medication is free to those most in need is key to success. In Ireland, the HSE programme advises all smokers to combine the quit service with stop-smoking medications.

Over 30% of people in Ireland have medical cards, which entitles them to a range of services and medicines free of charge. This means low-income smokers can access stop-smoking medications without denting their wallets.

In addition to affordability, rigorous logistical planning helps ensure that smokers have timely support to quit. "We have a national digital patient-management system, which allows advisers to schedule call-backs," Martina explains.

"It now also facilitates the electronic referral of smokers from all general practitioners in primary care into a centralized referral processing centre, after which they will be assigned to a stop-smoking adviser and service local to them."

High uptake of the cessation services has largely been driven by referrals from health professionals and well funded, active mass media campaigns.

The HSE and the National Clinical Effectiveness Committee of the Department of Health have developed best-practice guidelines on diagnosing and treating tobacco addiction, which will be shared with health professionals. This goes hand in hand with investment in people.

"Countries should agree to invest in standardized training for stop-smoking advisers," says Martina. "This will ensure that a specific role is identified for the treatment of tobacco dependence."

## Impact of COVID-19

Efforts to help people quit have never been more important in light of the coronavirus pandemic. COVID-19 has given many people a strong motivation to quit tobacco use, as smokers have a greater risk of developing a severe case of COVID-19 and dying from the disease.

Although the pandemic has further highlighted the risk of smoking, the picture is not straightforward. In some cases, stress and disruption from the pandemic have caused an increase in tobacco use among current users.

In a survey conducted by Ireland's HSE in April 2020, 35% of women and 26% of men who were using tobacco noted an increase in usage. As demonstrated by the HSE, redoubling efforts to commit to quit in light of the risks and pressures of COVID-19 is critical.

nicorette®
nicotine

# DOUBLE YOUR PATIENTS CHANCES OF QUITTING WITH NICORETTE QUICKMIST*


## STARTS TO RELIEVE CRAVINGS IN JUST 30 SECONDS **

*Compared to willpower alone. **Based on 2 x 1 mg dose

**Nicorette QuickMist1 mg/spray, oromucosal spray, solution**. **Composition**: One spray delivers 1 mg nicotine in 0.07 ml solution. 1 ml solution contains 13.6 mg nicotine. Excipient with known effect: Ethanol (less than 100 mg of ethanol/spray). Propylene glycol, Butylated hydroxytoluene. Pharmaceutical form: Oromucosal spray, solution. A clear to weakly opalescent, colourless to yellow solution. **Indications:** For the treatment of tobacco dependence in adults by relief of nicotine withdrawal symptoms, including cravings, during a quit attempt. Permanent cessation of tobacco use is the eventual objective. Nicorette QuickMist should preferably be used in conjunction with a behavioral support program. Dosage: Subjects should stop smoking completely during the course of treatment with Nicorette QuickMist. *Adults and Elderly:* The following chart lists the recommended usage schedule for the oromucosal spray during full treatment (Step I) and during tapering (Step II and Step III). Up to 4 sprays per hour may be used. Do not exceed 2 sprays per dosing episode and do not exceed 64 sprays (4 sprays per hour, over 16 hours) in any 24-hour period. **Step I: Weeks 1-6:** Use 1 or 2 sprays when cigarettes normally would have been smoked or if cravings emerge. If after a single spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. Most smokers will require 1-2 sprays every 30 minutes to 1 hour. **Step II: Weeks 7-9:** Start reducing the number of sprays per day. By the end of week 9 subjects should be using HALF the average number of sprays per day that was used in Step I. **Step III: Weeks 10-12:** Continue reducing the number of sprays per day so that subjects are not using more than 4 sprays per day during week 12. When subjects have reduced to 2-4 sprays per day, oromucosal spray use should be discontinued. To help stay smoke free after Step III, subjects may continue to use the oromucosal spray in situations when they are strongly tempted to smoke. One spray may be used in situations where there is an urge to smoke, with a second spray if one spray does not help within a few minutes. No more than four sprays per day should be used during this period. Regular use of the oromucosal spray beyond 6 months is generally not recommended. Some ex-smokers may need treatment with the oromucosal spray longer to avoid returning to smoking. Any remaining oromucosal spray should be retained to be used in the event of sudden cravings. *Paediatric population:* Do not administer this medicine to persons under 18 years of age. There is no experience of treating adolescents under the age of 18 with this medicine. Method of administration: After priming, point the spray nozzle as close to the open mouth as possible. Press firmly the top of the dispenser and release one spray into the mouth, avoiding the lips. Subjects should not inhale while spraying to avoid getting spray into the respiratory tract. For best results, do not swallow for a few seconds after spraying. Subjects should not eat or drink when administering the oromucosal spray. Behavioural therapy advice and support will normally improve the success rate. **Contraindications:** Hypersensitivity to nicotine or to any of the excipients. Children under the age of 18 years. Those who have never smoked. **Special warnings and precautions for use:** This medicine should not be used by non-smokers. The benefits of quitting smoking outweigh any risks associated with correctly administered nicotine replacement therapy (NRT). A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions: *Cardiovascular disease: Dependent smokers with a recent myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe cardiac arrhythmias, recent cerebrovascular accident and/or who suffer with uncontrolled hypertension* should be encouraged to stop smoking with non-pharmacological interventions (such as counselling). If this fails, the oromucosal spray may be considered but as data on safety in this patient group are limited, initiation should only be under close medical supervision. *Diabetes Mellitus.* Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when smoking is stopped and NRT is initiated as reduction in nicotine induced catecholamine release can affect carbohydrate metabolism. *Allergic reactions:* Susceptibility to angioedema and urticaria. *Renal and hepatic impairment:* Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects. *Phaeochromocytoma and uncontrolled hyperthyroidism:* Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines. *Gastrointestinal Disease:* Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions. Paediatric population: *Danger in children:* Doses of nicotine tolerated by smokers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be handled or ingested by children. *Transferred dependence:* Transferred dependence can occur but is both less harmful and easier to break than smoking dependence. *Stopping smoking:* Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, tacrine, clozapine and ropinirole. The plasma concentration of other medicinal products metabolised in part by CYP1A2 e.g. imipramine, olanzapine, clomipramine and fluvoxamine may also increase on cessation of smoking, although data to support this are lacking and the possible clinical significance of this effect for these drugs is unknown. Limited data indicate that the metabolism of flecainide and pentazocine may also be induced by smoking. *Excipients:* The oromucosal spray contains small amounts of ethanol (alcohol), less than 100 mg per dose (1 or 2 sprays). This medicinal product contains less than 1 mmol sodium (23 mg) per spray, i.e. essentially 'sodium- free'. This medicine contains 12 mg propylene glycol in each spray which is equivalent to 150 mg/mL. Due to the presence of butylated hydroxytoluene, Nicorette QuickMist may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. Care should be taken not to spray the eyes whilst administering the oromucosal spray.**Undesirable effects:** Effects of smoking cessation: Regardless of the means used, a variety of symptoms are known to be associated with quitting habitual tobacco use. These include emotional or cognitive effects such as dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, and restlessness or impatience. There may also be physical effects such as decreased heart rate; increased appetite or weight gain, dizziness or presyncopal symptoms, cough, constipation, gingival bleeding or apthous ulceration, or nasopharyngitis. In addition, and of clinical significance, nicotine cravings may result in profound urges to smoke. This medicine may cause adverse reactions similar to those associated with nicotine given by other means and these are mainly dose-dependent. Allergic reactions such as angioedema, urticaria or anaphylaxis may occur in susceptible individuals. Local adverse effects of administration are similar to those seen with other orally delivered forms. During the first few days of treatment irritation in the mouth and throat may be experienced, and hiccups are particularly common. Tolerance is normal with continued use. Daily collection of data from trial subjects demonstrated that very commonly occurring adverse events were reported with onset in the first 2-3 weeks of use of the oromucosal spray, and declined thereafter. Adverse reactions with oromucosal nicotine formulations identified from clinical trials and during post-marketing experience are presented below. The frequency category has been estimated from clinical trials for the adverse reactions identified during post-marketing experience. Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data). **Immune system disorders** Common Hypersensitivity Not known Allergic reactions including angioedema and anaphylaxis **Psychiatric disorders** Uncommon Abnormal dream **Nervous system disorders** Very common Headache Common Dysgeusia, paraesthesia **Eye disorders** Not known Blurred vision, lacrimation increased **Cardiac disorders** Uncommon Palpitations, tachycardia Not known Atrial fibrillation **Vascular disorders** Uncommon Flushing, hypertension **Respiratory, thoracic and mediastinal disorders** Very common Hiccups, throat irritation Uncommon Bronchospasm, rhinorrea, dysphonia, dyspnoea, nasal congestion, oropharyngeal pain, sneezing, throat tightness **Gastrointestinal disorders** Very common Nausea Common Abdominal pain, dry mouth, diarrhoea, dyspepsia, flatulence, salivary hypersecretion, stomatitis, vomiting Uncommon Eructation, gingival bleeding, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral Rare Dysphagia, hypoaesthesia oral, retching Not known Dry throat, gastrointestinal discomfort, lip pain **Skin and subcutaneous tissue disorders** Uncommon Hyperhidrosis, pruritus, rash, urticaria Not known Erythema **General disorders and administration site conditions** Common Burning sensation, fatigue Uncommon Asthenia, chest discomfort and pain, malaise. **MAH:** Johnson & Johnson (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland. **PA Number:** PA 330/37/13. **Date of revision of text:** PA 330/37/13: May 2019. Product not subject to medical prescription. Full prescribing information available upon request.

IE-NI-2000032

Attends®

40 Years

experience in care


# Secure Incontinence Protection. All Day, Everyday.

- Personalised product assessment
- Dedicated team of product advisors
- Training sessions with product demonstrations and samples
- E-learning support & marketing materials

**Contact us today for more information:**

01924 669 260

www.attends.co.uk

# Heart Disease: *Not Just for Men*

***Written by Dr Catherine Riordan, Women's Health Specialist, The Menopause Hub***

Cardiovascular disease, mainly heart attack and stroke, is the biggest killer of women in Ireland, and worldwide. In fact, one in two women will die of cardiovascular disease in Ireland. Yet research carried out by the Irish Heart Foundation showed that less than one in five Irish women were aware of this. Heart disease is perceived as a man's disease. However, this is not necessarily the case.

The incidence of cardiovascular disease (CVD) in premenopausal women is three times lower than in men of the same age. By the time women reach age 75-79, the incidence is equal. This appears to be due to a protective effect of estrogen which is lost at menopause, when ovarian estrogen production fails.

Premature menopause occurring under the age of 40, increases the risk of myocardial infarction by two to threefold. Oophorectomy under the age of 40 increases it even more so. Interestingly, total mortality is increased even if oophorectomy is carried out after the onset of natural menopause, up to the age of 60, largely due to Coronary Artery Disease (CAD). This suggests a degree of protection by the ovary even beyond menopause.

Preventative measures against CAD such as statins and aspirin are successful in terms of mortality reduction in men. However, the same benefit is not seen in women. Only lifestyle changes show any benefit. However, this is only half the benefit seen with the use of estrogen Hormone Replacement Therapy (HRT).

Studies suggest a window of opportunity within which women will benefit from estrogen replacement, if started within 10 years of their last period or below the age of 60. Women initiating HRT within this window gain a 50% reduction in the development of CVD and approx 40% reduction in all cause mortality. The benefit has been seen to persist for at least 16 years in a long-term Danish study. Despite women's fears of breast cancer, CVD is the leading cause of death in women, with the risk of death from CAD at 31% compared to a 3% risk of dying from breast cancer. So, a 50% reduction in risk is highly significant. Beyond that window, however, the initiation of HRT may increase the incidence of coronary events. There are several potential reasons for this window:

Increases in weight, blood pressure and blood glucose are all risk factors for the development of CAD, but the most important change occurring with menopause appears to be the increase in total cholesterol. This is largely accounted for by a rise in LDL-C which contributes to the formation of atherosclerotic plaques. The further post menopause, the more atherosclerosis women are likely to have developed, with a resulting narrowing of the coronary arteries.

Multiple factors lead to reduced blood flow in all vascular beds and a vasoconstrictor effect of acetylcholine. Estrogen generally improves all the responsible parameters, often restoring them to the premenopausal range, resulting in increased blood flow and a vasodilatory response. As cholesterol levels increase post menopause, so does endogenous 27-hydroxycholesterol. This competes with estrogen at estrogen receptor sites in the endothelium and may prevent its direct vasodilatory action. The direct effects of estrogen on the endothelium are thought to be more important than the changes in lipids and lipoproteins. The more advanced the atherosclerotic plaque formation, the less unaffected endothelium is available to estrogen and the less effective it can be.

Not only do we see a lack of benefit for older women commencing HRT de novo, there may be an increase in coronary events. This is likely due to metabolites of oral estrogen which dissolve part of the gelatinous plaque, leading to instability, rupture and potentially coronary thrombosis. The same increase in risk is not seen with transdermal estrogen. The increased risk is also not seen in women who are on a statin, as statins stabilise plaques.

There are significant differences between oral and transdermal estrogen. Oral estrogen undergoes first pass liver metabolism, resulting in metabolites which affect the coagulation cascade, resulting in an increased risk of venous thromboembolism (VTE) and stroke. In young women without other risk factors, the background risk of VTE or stroke is extremely low and the small associated increase in risk is negligible. Transdermal estrogen does not undergo first pass metabolism and is not associated with an increase in VTE or stroke risk. It is, therefore, safer for younger women with risk factors or for older women in whom the risk is naturally higher due to age alone. For older women suffering from significant symptoms of menopause and who wish to use HRT, low dose transdermal estrogen is also the safer option as it is also less likely to lead to coronary events, as noted earlier.

**MENOPAUSE**

# What Women Need to Know

*Written by Dr Conor Harrity, Medical Director, The Menopause Hub, Consultant Gynecologist at Beaumont & Rotunda Hospitals*

Osteoporosis is defined by the World Health Organization as a degenerative bone disease characterized by low bone mass and microstructural deterioration of bone tissue, which leads to bone fragility and increased risk of fractures (WHO, 1994). Postmenopausal females are the highest risk group for fractures, the majority of which are preventable.

Lack of exposure to estrogen, smoking, specific medications (glucocorticoids, PPIs, anti-convulsants, thiazolidinediones, aromatase inhibitors, antigoagulants, lithium) and certain medical conditions (hyperthyroidism, rheumatoid arthritis, malabsorption, cancer, hepatic/renal disease) are causative factors. It is the most common global metabolic bone disease, with the International Osteoporosis Foundation reporting that 1 in 3 women over 50, and 1 in 5 men will experience osteoporotic fractures in their lifetime and estimated to affect over 200 million people. In the US 10 million cases of osteoporosis have been diagnosed, of which 80% are women. With an additional 44 million having low bone density, (National Osteoporosis Foundation ,2020). Data from the UK reports approximately 536,000 fragility fractures occurring annually as a result. Ireland's climate plays a role in the development of osteoporosis, as the northerly latitude decreases exposure of UV light between October and March resulting in low levels of vitamin D.

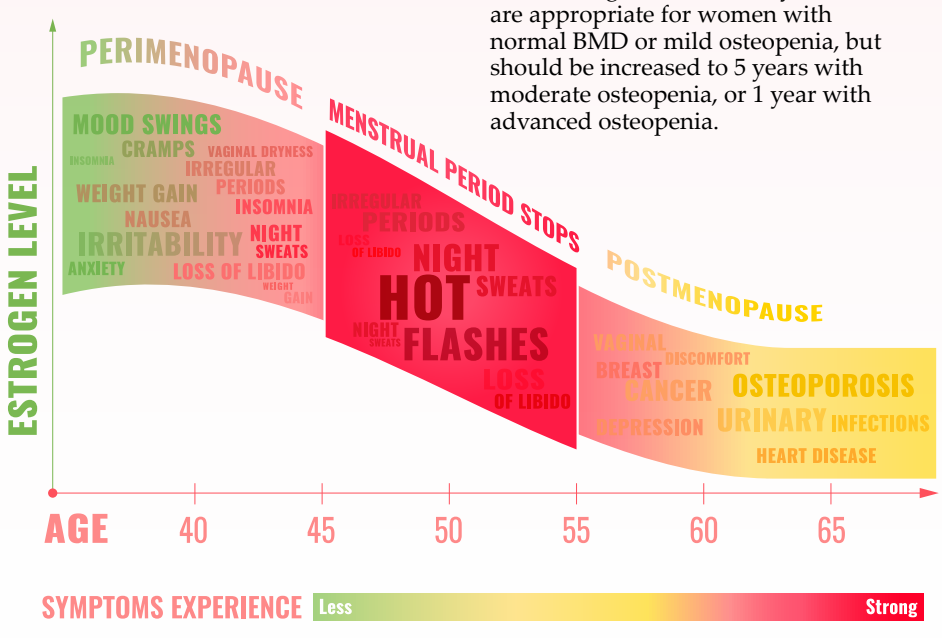
It is estimated that around 300,000 people living in Ireland have Osteoporosis, but only 15% are clinically diagnosed, and that 1 in 2 females over the age of 50 will develop an osteoporosis related fracture over their lifetime (Irish Osteoporosis society).

Dual-energy x-ray absorptiometry (DEXA) is the gold standard for evaluation of Bone Mineral Density (BMD). Peripheral DEXA is used to measure BMD at the wrist; it may be most useful in identifying patients at very low fracture risk who require no further work up. DEXA of the femoral neck is the method of choice in those displaying a higher fracture risk.

A T-score is calculated by comparing the BMD value with that of controls at their peak bone density, while a Z-Score is compared to an age-matched normal mean. World Health Organization criteria define a normal T-score value as within 1 standard deviation (SD) of the mean BMD value in a healthy young adult. Variations in these standards assist in diagnosis.

- T-score of –1 to –2.5 SD indicates osteopenia (Low bone mass)
- T-score of less than –2.5 SD in lumbar spine or femoral neck indicates osteoporosis (ISCD)
- T-score of less than –2.5 SD with fragility fracture(s) indicates severe osteoporosis

A DEXA scan should be performed for women aged >65 (Men >70). For postmenopausal women <65 (Men <70) it should be recommended only in the presence of additional risk factors such as low body weight, previous fracture, the use of high risk medication, or the presence of associated diseases. Rescreening intervals of 15 years are appropriate for women with normal BMD or mild osteopenia, but should be increased to 5 years with moderate osteopenia, or 1 year with advanced osteopenia.




The Fracture risk assessment tool (FRAX) can be used as a prognostic marker. It calculates the 10 year fracture probability above that of a 65 year old Caucasian female without risk factors. The result can be used to assist when determining if BMD measurement or active treatment may be necessary, however, the thresholds for drug treatment have not been proven to be effective for fracture prevention. A particularly useful role for this marker is to assist when deciding if a DEXA scan is needed for women aged 40-65.

Treatment of low bone density includes a combination of dietary, lifestyle and medical interventions.

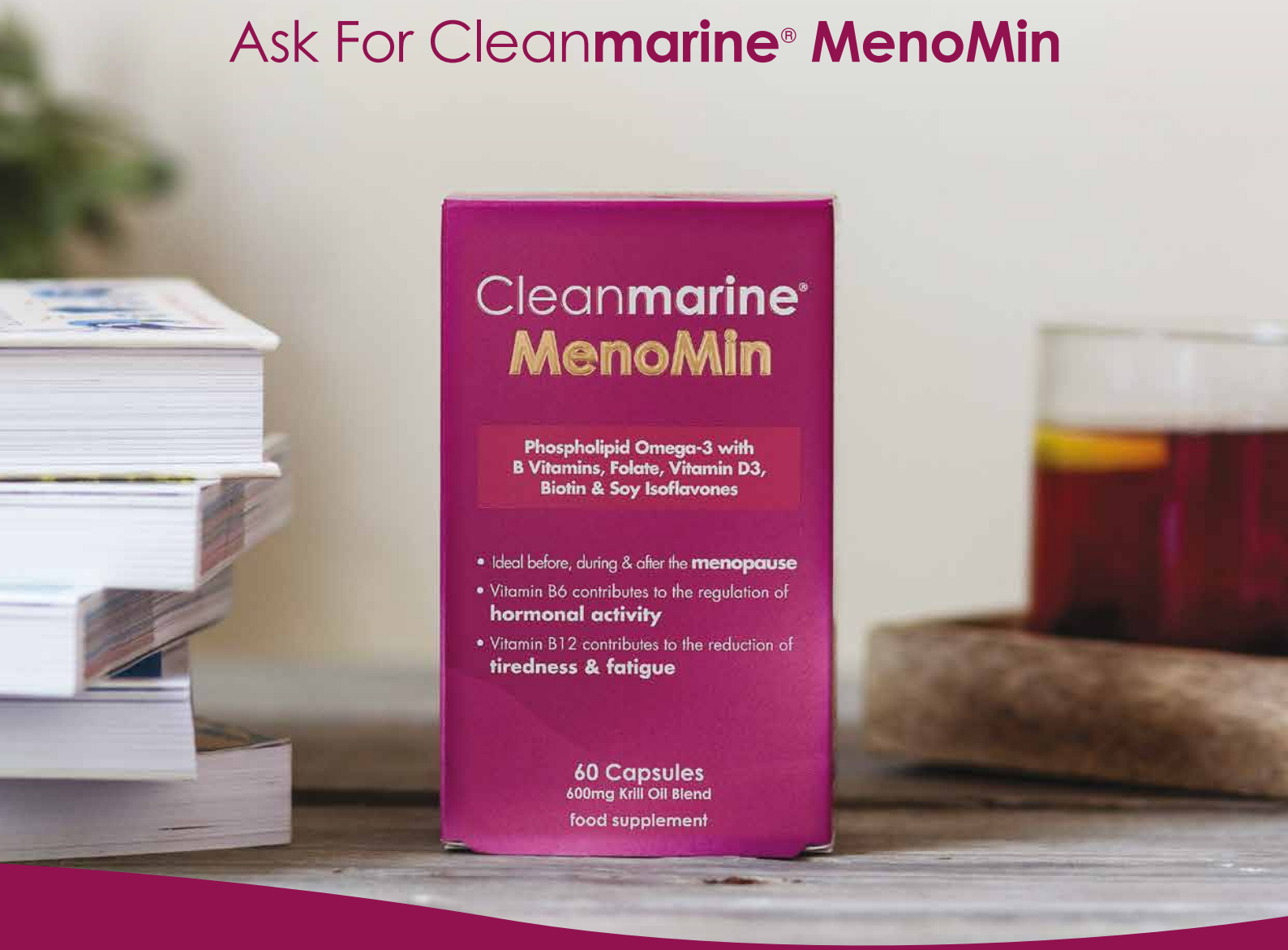
Optimisation of calcium and vitamin D status are important first line interventions. Risk appropriate exercise and prevention of falls are also needed. For women of low to medium risk for osteoporotic fracture, the consideration of hormone replacent therapy in the decade following menopause can be considered. In these patients Oestrogen replacement has been suggested to lead to a higher improvement in BMD, and better quality bone than alendronate.

For patients at high risk of fracture Anti-Resorptive treatment with bisphosphonates, Denosumab or SERMs are appropriate interventions. For very high-risk patients formation stimulating agents such as teripratide, abaloparatide or romosozumab (sclerostin antibody) can be considered, followed by an inhibitor of bone resorption. Unfortunately the benefit of oestrogen therapy on bone density is lost within a few months of stopping treatment.

This is also seen with denosumab, raloxifene and teriparatide. After discontinuation of HRT in patients with significant osteopenia a short course of alendronate or zoledronate infusion may be considered.

# MENOPAUSAL SUPPORT?

## Ask For Cleanmarine® MenoMin




- Omega 3 Phospholipids
- Vitamins B1, B2, B6 & B12
- Soy Isoflavones
- Vitamin D3
- Rosemary Extract
- Biotin
- Folate

Exclusive To Health Stores & Pharmacies

IRISH BRAND

# Effects of Menopause on Sleep

*Written by Dr Catherine Riordan, Women's Health Specialist, The Menopause Hub & Michele Pippet, Psychologist & Counsellor at The Menopause Hub*

The fall in estrogen and progesterone levels that accompanies perimenopause and menopause leads to sleep difficulties for up to 60% of women.

Insomnia is difficulty falling asleep, staying asleep or early morning awakening with resultant daytime dysfunction. This dysfunction can manifest in many ways, such as fatigue, poor cognitive function, mood disturbance, irritability, anxiety, slow reaction times and headaches, all of which can be disabling and disruptive to day to day activities.

Chronic insomnia, where this happens at least three nights a week over more than 3 months, is associated with potential long term health risks including cardiovascular disease, diabetes, obesity, cognitive decline, depression and increase in general mortality.

Hot flushes and night sweats, bladder issues, aches and pains and anxiety can all result from low estrogen levels and, for many, restoration in the form of Hormone Replacement Therapy (HRT) can reduce or eliminate these, thus restoring sleep.

Progesterone has direct sleep-inducing effects on the brain and the addition of progesterone can help in sleep restoration. For women who cannot use HRT, other medications such as clonidine, SSRIs, SNRIs or gabapentin may be used to reduce vasomotor symptoms and can be helpful. Melatonin is vital for sleep and its secretion falls with age.

Estrogen and progesterone influence melatonin production, so their decline further compounds the problem. Sleep apnoea becomes more common with menopause and should be considered in women who fail to respond to treatment.

Education about sleep in terms of what is a 'normal' quantity and quality, as well as cognitive behavioural strategies, have been found to be effective for people experiencing sleep problems. It can be useful either as an alternative to or in combination with medical treatments.

Cognitive behavioural Therapy (CBT) is an evidence-based intervention; a short-term, skills-focused form of psychotherapy that concentrates on the interaction between thoughts, feelings and behaviours. The cognitive part looks at the way we think about the symptom/ problem and how this affects the way we feel.

The behavioural part looks at ways we can change our behaviour to promote better coping skills and wellbeing. Psycho-education and cognitive behavioral strategies can be used to develop a calmer view of a situation, practical ways of managing problems and new coping skills.

Stress and worry about not sleeping is often a key problem and women going through menopause often worry at night about sleeplessness and its effects on the following day.

Excessive focus on missing sleep adds pressure to sleep. This raises anxiety levels and physiological arousal which then, in turn, makes sleep less likely and undermines sleep quality. During the day, attention is focused on missed sleep and so there is a hypervigilance to tiredness.

So, sleep is not just a nighttime process of worry. It actually spans the 24 hour period in a vicious cycle. The body's stress response is an important factor in insomnia and the body may be in the opposite physiological state to that required in order to fall asleep.

Sleep psycho-education allows unhelpful beliefs and negative cognitions about sleep to be identified, explored and challenged. We often focus on the worst possible outcome and ignore any middle ground.

Once anxious or frustrated cognitive responses have been identified, calmer more supportive thoughts can be developed. There is good evidence that relaxation is helpful in improving sleep and diaphragmatic or paced breathing and mindful relaxation is good for switching off the stress response and making sleep more likely.

There are also a number of behavioural interventions to enhance general sleep quality.They involve sleep habits and the environment, stimulus control and associating bed with sleep, wind-down routines and relaxation, sleep scheduling and managing daytime tiredness.

The aim is to change some of the thinking and behavioural patterns, to re-establish a good pattern of wakefulness in the day and sleepiness at night and strong associations between bed and sleep. While HRT brings relief for most women suffering insomnia due to menopause-related hormone deficiency, psychological interventions such as CBT can be a useful additional tool.

It is particularly beneficial for women who cannot take HRT for any reason. A multidisciplinary approach is often required and can be very effective.

reviveactive™

# Dear menopause,

## This is my body. My journey. I am taking control.


SACHET & CAPSULE FORMULA

A **new** ***super supplement*** containing a premium blend of 30 active ingredients to take during and after **menopause.**

**30 ACTIVE INGREDIENTS**

- ✓19 Vitamins & Minerals
- ✓4 Digestive Enzymes
- ✓3 Plant Extracts
- ✓Omega 3 DHA
- ✓3 Strains of Live Friendly Bacteria

Guaranteed Irish LOVE IRISH FOOD

CALL: **091 769803** | EMAIL: **INFO@REVIVEACTIVE.COM** | WEB: **REVIVEACTIVE.COM**

# COLD & FLU?


MA holder:
Rowa Pharmaceuticals Ltd.,
Newtown, Bantry,
Co. Cork, Ireland.
PA0074/067/006
Date of preparation: 6/21 CCF: 23764

*Marketed by*
ROWEX®

## If you need effective relief **take it. If you don't don't.**

ABBREVIATED PRESCRIBING INFORMATION

Product Name: Brupro Cold & Flu 200 mg/30 mg film-coated tablets. Composition: Each film-coated tablet contains 200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride. Description: Yellow, round, film-coated tablets. Diameter: approx. 11 mm, height: approx. 5 mm. Indication(s): Adults and adolescents aged 12 years and older: For the symptomatic relief of nasal/sinus congestion with headache, fever and pain associated with the common cold and flu. Dosage: 1 tablet every 6 hours if necessary. For more intense symptoms, 2 tablets every 6 hours if necessary, to a maximum total daily dose of 6 tablets (equivalent to 1200 mg ibuprofen and 180 mg pseudoephedrine hydrochloride). The maximum total daily dose of 6 tablets must not be exceeded. For short-term use. The patient should consult a doctor if symptoms worsen. The maximum duration of treatment is 4 days for adults and 3 days for adolescents aged 12 years and older. In situations where the symptoms predominantly consist of either pain/fever or nasal congestion, administration of single entity products is to be preferred. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. The tablets should be swallowed whole without chewing with a large glass of water, preferably during meals. Contraindications: Hypersensitivity to ibuprofen, pseudoephedrine hydrochloride or to any of the excipients; Patients aged under 12 years; Pregnant women during the third trimester of pregnancy; Breast-feeding mothers; History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding); Severe heart, liver or renal (glomerular filtration below 30ml/min) failure; Conditions involving an increased tendency to bleeding; Patients with known hypersensitivity or who have experienced asthma, urticaria, or allergic-type reactions after taking ibuprofen, aspirin or other NSAIDs; Severe cardiovascular disorders, coronary heart disease (heart disease, hypertension, angina pectoris), tachycardia; Hyperthyroidism; Diabetes; Pheochromocytoma; History of stroke or presence of risk factors for stroke; History of myocardial infarction; Closed-angle glaucoma; Urinary retention; History of seizures; SLE; Use of MAOIs. Warnings and Precautions for Use: Concomitant use with other NSAIDs including cyclo-oxygenase (COX)-2 selective inhibitors should be avoided. If symptoms persist beyond the recommended maximum duration of treatment with this medicinal product (4 days for adults and 3 days for adolescents), measures to be taken should be re-evaluated, in particular the possible usefulness of an antibiotic treatment. Acute rhinosinusitis, suspected to be of viral origin, is defined by moderate intensity, bilateral rhinological symptoms dominated by nasal congestion with serious or puriform rhinorrhea, occurring in an epidemic context. The puriform appearance of rhinorrhea is common and does not systematically correspond to bacterial superinfection. Sinus pains, during the first days of the illness, are associated with congestion of the sinus mucosa (acute congestive rhinosinusitis) and most often are resolved spontaneously. In the event of acute bacterial sinusitis, antibiotic therapy is justified. Special warnings related to pseudoephedrine hydrochloride: Discontinue in development of hypertension, tachycardia, palpitations, cardiac arrhythmias, nausea or any neurological signs such as onset or worsening of headache. Refer to the SPC for other warnings on use and discontinuation requirements. Precautions for use related to pseudoephedrine hydrochloride: Discontinue treatment several days before surgery if volatile halogenated anaesthetics are to be used due to risk of acute hypertension. Athletes: Possibility of positive results in doping tests. Interference with serological testing: Pseudoephedrine has the potential to reduce iobenguane i-131 uptake in neuroendocrine tumors, thus interfering with scintigraphy. Special warnings related to ibuprofen: Bronchospasm may be precipitated in patients suffering from, or with a history of bronchial asthma or allergic disease. Do not take in cases of asthma without prior consultation with a doctor, as an acute asthma attack can be precipitated, particularly when allergic to acetylsalicylic acid or an NSAID. Patients who have asthma associated with chronic rhinitis, chronic sinusitis and/or nasal polyposis have a higher risk of allergic reactions when taking acetylsalicylic acid and/or NSAIDs. Refer to the SPC for more information on medication overuse headache (MOH), blood clotting disorders, gastro-intestinal bleeding, ulceration or perforation (discontinue immediately in these cases), history of gastro-intestinal disease (ulcerative colitis, Crohn's disease), alcohol, risk of arterial thrombotic events (particularly at a high ibuprofen dose of 2400 mg/day), serious skin reactions. Discontinue at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Consider carefully in uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease and high doses (2400 mg/day) should be avoided. Precautions for use related to ibuprofen: Monitor the elderly carefully, due to increased frequency of NSAID-related undesirable effects, particularly gastro-intestinal bleeding and perforation, which can be fatal. Monitor in history of gastro-intestinal disease (such as peptic ulcer, hiatus hernia or gastrointestinal bleeding). Monitor urine output and renal function initially in heart failure, chronically impaired renal or hepatic function, patients taking diuretics, hypovolaemia as a result of major surgery. If visual disturbances occur during the course of treatment, a full ophthalmological examination should be carried out. Interactions: Refer to the SPC for detailed information on interactions. Combination of pseudoephedrine with: Non-selective MAOIs (iproniazid); Other indirectly-acting, orally or nasally administered sympathomimetics or vasoconstrictor agents, α-sympathomimetic drugs, phenylpropanolamine, phenylephrine, ephedrine, methylphenidate; Reversible inhibitors of monoamine oxidase A (RIMAs), linezolid, dopaminergic ergot alkaloids, vasoconstrictor ergot alkaloids: Volatile halogenated anaesthetics: Guanethidine, reserpine and methyldopa: Tricyclic antidepressants; Digitalis, chinidine or tricyclic antidepressants. Concomitant use of ibuprofen with: Other NSAIDs, including salicylates and COX-2 selective inhibitors; Digoxin; Corticosteroids; Anti-platelet agents; Acetylsalicylic acid; Anticoagulants: (e.g.: warfarin, ticlopidine, clopidogrel, tirofiban, eptifibatide, abciximab, iloprost); Phenytoin; Selective serotonin reuptake inhibitors (SSRIs); Lithium; Probenecid and sulfinpyrazone Diuretics, ACE inhibitors, beta-receptor blockers and angiotensin-II antagonists; Potassium sparing diuretics; Methotrexate; Ciclosporin; Tacrolimus; Zidovudine; Sulphonylureas; Quinolone antibiotics; Heparins; Gingko biloba. Pregnancy and Lactation: Contra-indicated during breastfeeding and the third trimester of pregnancy and should only be given if clearly necessary during the first and second trimester. Ability to Drive and Use Machinery: Minor or moderate influence on the ability to drive and use machines. Patients who experience dizziness, hallucinations, unusual headaches and visual or hearing disturbances should avoid driving or using machinery. Single administration or short-term use of this medicine does not usually warrant the adoption of any special precautions. Undesirable Effects: Common: Gastrointestinal discomfort, dyspepsia, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation, minor gastrointestinal blood loss in rare cases leading to anaemia. Refer to the SPC for other undesirable effects. Marketing Authorisation Holder: Rowa Pharmaceuticals Ltd., Bantry, Co. Cork. Marketing Authorisation Number: PA0074/067/006. Further information and SPC are available from: Rowex Ltd., Bantry, Co. Cork. Freephone: 1800 304 400 Fax: 027 50417 . E-mail: rowex@rowa-pharma.ie Legal Category: Not Subject to medical prescription. Date of Preparation: May 2021. Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie) or by emailing Rowex pv@rowa-pharma.ie

# Opportunity for Pharmacy to Empower Women

A survey of 2,400 women[1], commissioned by the makers of Active Iron, leading experts in oral iron, shows half of women (51%) get tiredness and fatigue regularly due to their period, with 67% not realising that this could be due to their iron levels.

In addition, over three-quarters of women (82%) aren't aware of how much iron is lost because of their period. And worryingly, 82% have come to accept experiencing symptoms regularly because of their menstrual cycle as the norm.

Dr Aoibhe O'Driscoll of Blackrock Medical Centre, Women's Health Clinic and a menopause specialist in Cork says, "Periods, especially heavy periods, are a leading cause of iron loss worldwide. This means it is common for symptoms such as fatigue and tiredness to be experienced. The survey shows that many women are suffering in silence and, considering women will on average spend a combined total of 10 years menstruating, a huge portion of their life could be spent feeling less than their best, and this needs to change."

Tiredness and fatigue are the symptoms of menstruation that women are most likely, by far, to put up with (46%). 60% say they sleep more to combat the tiredness from their cycle, while coffee (36%) and energy drinks (17%) are also popular options to help restore energy levels.

In terms of seeking advice on menstrual symptoms, while 47% of women will look online, only 40% have consulted their GP, 15% a gynaecologist, and 10% their pharmacist.

Iron supplementation is generally most helpful for women experiencing fatigue on account of menstruation, Dr Aoibhe O'Driscoll explains.

"On average, women will lose around 30-50ml of blood during their period, which will contain between 220mg and 250mg of iron. To put that in context, you would need to eat 1kg of spinach, over 12 servings, to generate the equivalent iron stores."

Dr. Aoibhe O'Driscoll continues "There's a significant opportunity for pharmacy staff to provide support and advice to empower women with periods to make choices that can sustain and build their iron stores, haemoglobin levels and energy. We can start by recognising the symptoms frequently being faced by women taking oral iron. We can be proactive in empowering women to manage this, whether it be via diet, lifestyle and/or supplement support."

> "There's a significant opportunity for pharmacy staff to provide support and advice to empower women with periods to make choices that can sustain and build their iron stores, haemoglobin levels and energy"

Of those who have considered that their iron levels may be impacted by their period, 45% have tried an iron supplement. However, 45% of these women admit that they have stopped taking it because of the side effects, which can include constipation, bloating and nausea.

**Clinical Study**

A new study has found that Active Iron is six times less likely to cause gut irritation compared to previous oral iron, resulting in a four-fold improvement in adherence to treatment. The product also showed a 94% increase in iron stores, with a resulting major improvement in energy levels.

The research reinforced the fact that Active Iron is an effective product that pharmacy staff and healthcare professionals can confidently recommend, which can increase iron levels and help alleviate some of the concerns that customers might have when it comes to side effects associated with iron supplements.

University College Dublin School of Medicine Professor and Pharmacist Mark Ledwidge, who helped develop Active Iron, says, "This study helped reveal the scale of the gut irritation problem, due to oral iron, amongst women. As well as gut discomfort, 63% of participants had insufficient iron stores. Gut side effects are the main reason women stop supplementing with iron, so it's welcome news that Active Iron can reduce the gut discomfort while improving compliance, iron stores, haemoglobin levels and energy for these women."

On the back of this new research, Active Iron has launched a 'Better Days. Period' campaign, which aims to empower women to take action to feel less tired and more themselves during their menstrual cycle. The marketing campaign spans PR, social media, digital activation, and influencers, and encourages women to seek advice from pharmacy teams.

Claire Lynch, Brand & Communications Lead for Active Iron, adds, "The research presents a big opportunity for pharmacy staff to provide guidance to women who might have accepted feeling tired as the norm during their menstrual cycle. In fact, more than seven in ten women, 74%, expressed interest in taking an iron supplement to support energy levels, so we hope the new campaign encourages them to seek help from healthcare professionals and stop 'putting up' with ongoing symptoms such as tiredness and fatigue a result of blood loss during menstruation."

Dr Aoibhe O'Driscoll, Blackrock Medical Centre, Women's Health Clinic

Following the study results, Active Iron have launched a higher dose called Active Iron Advance. Active Iron was shown to be clinically effective in increasing iron stores and resulting energy levels whilst reducing the negative side effects of oral iron.[2]

*30-days supply of Active Iron Advance, produced by Solvotrin Therapeutics in Cork, has an RRP of €21.99*


**References**

1. Survey conducted by 3GEM with 2400 women in the UK
2. Clinical study on behalf of Active Iron

# Imvaggis®

estriol 0.03mg pessary

*Restoring Peace*
FROM WITHIN

# VAGINAL ATROPHY

## UNDERDIAGNOSED AND UNDERTREATED[1]

## **IMVAGGIS** (ESTRIOL) 0.03MG PESSARY FOR **VAGINAL ATROPHY** IN POSTMENOPAUSAL WOMEN[2]

An **ultra-low dose,** smooth estriol pessary that is easily inserted **without the need for an applicator,** designed with the patient in mind[2,3]

**Imvaggis** significantly **improves** the symptoms of vaginal atrophy, **restores** the vaginal flora by improving the physiology of the vaginal epithelium vs placebo at 12 weeks (P<0.001)[2, 4]

For more information, visit **www.imvaggis.ie**


PRESCRIBING INFORMATION
**Imvaggis (Estriol) 0.03 mg pessary**
For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).
**Presentation:** Each pessary contains 0.03 mg of estriol. **Indication:** Local treatment of vaginal symptoms of estrogen deficiency in postmenopausal women. **Dosage and Administration:** During the first 3 weeks of treatment, 1 pessary is administered daily. Thereafter, a maintenance dose of 1 pessary twice a week is recommended. The pessary should be introduced deeply into the vagina, preferably in the evening before going to bed. For initiation and continuation of treatment, the lowest effective dose for the shortest duration should be used. For full details of usage please refer to the SPC. **Contraindications:** Hypersensitivity to estriol or any of the excipients; known, past or suspected breast cancer; known or suspected estrogendependent malignant tumours (e.g. endometrial cancer); undiagnosed genital bleeding; untreated endometrial hyperplasia; previous or current venous thromboembolism (deep vein thrombosis, pulmonary embolism), known thrombophilic disorders, active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction); acute liver disease or history of liver disease whilst liver function tests are abnormal; porphyria. **Warnings and Precautions:** Local estrogen therapy should only be initiated for symptoms that adversely affect quality of life. The risks and benefits should be reviewed annually and therapy should only be continued as long as the benefit outweighs the risk. Estriol must not be combined with estrogen preparations for systemic treatment. A personal and family medical history should be taken before initiating or reinstituting estriol treatment. Periodic checkups are recommended during treatment. Frequency and nature of the examinations should be adapted to the individual woman. Investigations, including mammography are recommended according with current screening practices. Patients should be closely supervised if any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment since they may recur or be aggravated during treatment with Estriol: leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders; risk factors for estrogen-dependent tumours; hypertension; liver disorders; diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; history of endometrial hyperplasia; epilepsy; asthma and otosclerosis. Estriol should be discontinued if a contraindication is discovered or the following occur: jaundice or deterioration in liver function; significant increase in blood pressure; new onset of migraine-type headache; pregnancy. An increased risk of endometrial hyperplasia or uterine cancer has not been attributed to treatment with estriol by vaginal use. Endometrial safety of long-term (>1 year) or repeated use of local vaginally administered estrogen is uncertain. Therefore, if repeated, treatment should be reviewed at least annually. If break through bleeding and spotting occurs during therapy or continues after treatment has been discontinued the reason should be investigated. Unopposed estrogen stimulation may lead to premalignant transformation in the residual foci of endometriosis. The following risks have been associated with systemic HRT and apply to a lesser extent for HRT products for vaginal application where the systemic exposure to the estrogen is very low, however they should be considered in case of long term or repeated use: Breast cancer; ovarian cancer; venous thromboembolism, coronary artery disease, ischaemic stroke and certain other conditions including fluid retention. Therefore, patients with cardiac or renal dysfunction should be carefully observed. Please refer to the SPC for full details. **Interactions:** No clinically relevant interactions with other medicinal products are expected following vaginal administration of low-dose estriol pessaries. If estriol pessaries are used simultaneously with condoms made of latex, it can decrease the tensile strength and thus impair the safety of condoms. **Pregnancy and breastfeeding:** Estriol pessaries are not indicated in pregnancy or during breastfeeding. If pregnancy occurs during treatment with Estriol pessaries, the treatment should be withdrawn immediately. **Undesirable effects:** At the beginning of treatment, when the vaginal epithelial layers are still atrophic, local irritation may occur as a sensation of heat, pain and/or itching. They are often transient and of mild intensity. The following commonly (>1/100; <1/10) occur: vulvovaginal burning, pruritus, pain and dysuria. The following are uncommon (≥1/1,000; <1/100): vaginal discharge, anorectal discomfort. For further information on side effects and risk estimates, please consult the SPC. **Overdose:** Toxicity for estriol is very low. Overdose of Estriol pessaries by vaginal application is unlikely. Symptoms that may occur in the case of a high dose accidentally ingested are nausea, vomiting and vaginal bleeding in females. **Legal category:** POM. **Marketing Authorisation number:** PA 1054/005/001. **Marketing Authorisation Holder:** Laboratoires Besins International, 3 rue du Bourg L'Abbé, 75003 Paris, France. **Date of preparation of Prescribing Information:** October 2019.BHUK/2019/180-ROI

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie
Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 01-4004466 or Email: pharmacovigilance@besinshealthcare.com


**References**
1. Nappi RE et al. Gynecol Endocrinol. 2016;32(8):602–6.
2. Imvaggis (estriol) 0.03mg pessary Summary of Product Characteristics. Available from https://www.medicines.ie/medicines/imvaggis-0-03-mg-pessary-34870/spc#tabs Last accessed August 2021
3. Data on File IMV/2020/017
4. Griesser H, et al. Maturitas; 2012; 71(4): 360 - 368


Job code: IMV/2021/026-ROI
Date of preparation: August 2021

BESINS HEALTHCARE
Innovating for Well-being

# Menopause - *What has Changed and What we know Now*

***In 1992, Premarin was the best-selling medication in the USA. Since the prescriptions for Hormone Replacement Therapy plummeted around the world. But a lot has changed since the WHI trial and we now have a better understanding of the risks and benefits associated with using HRT.***

***Written by Dr. Caoimhe Hartley, GP and Menopause Specialist, The Menopause Health Clinic, Dalkey***

Menopause is the term for our last menstrual period. Perimenopause is the term given to the years leading up to this final period and reflects a change in the production of our ovarian hormones. In perimenopause, our ovarian production of oestrogen (and progesterone) starts to become increasingly erratic and irregular, leading to an excessive production of oestrogen at times.

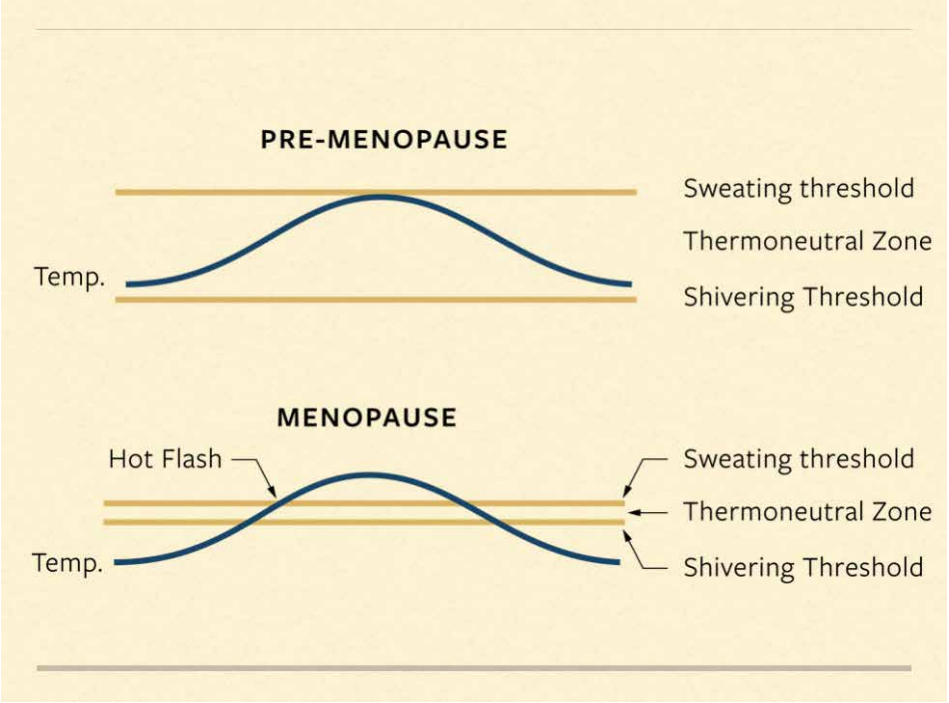
This causes pronounced "PMS-type" symptoms such as breast tenderness, headaches, irritability and low mood. It often coincides with a change in our menstrual cycle. Some women experience a longer or shorter gap between their periods or a change in how heavy their periods are. This excess of oestrogen production in perimenopause can stimulate the growth of fibroids and may contribute to flooding and menorrhagia.

Menopause itself occurs when the ovaries are no longer able to respond to increasing levels of FSH (from the pituitary gland, trying to stimulate them to ovulate and produce oestrogen) and results in a flat-line of low oestrogen levels. Mood symptoms are often a little better when periods have stopped completely because the hormonal environment is more stable. However other symptoms are more prominent, including vasomotor symptoms and vaginal atrophy.

Hot flushes (and night sweats) happen due to the thermostat in our brain becoming more sensitive and over-reacting to small changes in our core-body temperature.

Approximately 80% of women will experience them and they last an average of 5-8 years.

There are many different approaches to managing both the symptoms and long term health changes that happen with perimenopause and menopause.




Lifestyle interventions such as reducing alcohol, caffeine and increasing exercise can have a beneficial impact on long term health outcomes. However for many women, despite these lifestyle changes, their symptoms can persist and adversely impact their quality of life, relationships and work.

There are benefits and risks associated with hormonal therapy for menopausal symptoms.

With regards to managing vasomotor symptoms, oestrogen is the most effective treatment. It has the potential to improve quality of life, wellbeing and reduce the risks of osteoporotic fracture and cardiovascular disease.

There are other, less well-known symptoms of the menopausal transition that can have meaningful impact on quality of life. Reduced verbal fluency and forgetfulness are some of the more common symptoms that I would hear about on a daily basis. They are highly distressing.

It reflects the picture that menopause is really a "neuroendocrine ageing process".[1]

Clinically significant reduction in cognition occurs in approximately 10% of menopausal women. This may be due to the fact that our hippocampus and prefrontal cortex are peppered with oestrogen receptors. We have growing evidence that HRT may have a positive impact on this and that women who receive HRT after oophorectomy have been demonstrated to maintain their verbal memory in comparison to age-matched, oopherectomised women

*"Of note, observational evidence suggests that taking hormone therapy does not further alter the risk for breast cancer in women with a family history of breast cancer"*

without HRT. The Baltimore Longitudinal Study of Ageing showed that women who had taken HRT had better blood flow in the hippocampal area later in life and performed better in memory tests. The research looking at verbal memory scores would suggest that the decline starts in late perimenopause (and is not age-dependent) and is worst during the late transition. At this point in time, whether HRT provides protection against cognitive ageing (or Alzheimer's Dementia) is still unclear and requires more research.

Hormone therapy comes in different forms, regimens, doses and delivery methods.

The estrogen most commonly prescribed is 17-beta oestradiol which differs from conjugated equine estrogen, used in the Women's Health Initiative Study. Although the efficacy of conjugated equine estrogens and estradiol are similar, there are differences with regards to risk and other outcomes. Cognitive outcomes, for example differ depending on the type of estrogen used with estradiol providing more robust anxiolytic, antidepressant effect.[2]

So who cannot take HRT - what are the absolute contraindications?

Having an acute hormone-dependent breast cancer, active liver disease, acute coronary disease or VTE, undiagnosed vaginal bleeding or untreated hypertension would all be considered contraindications to HRT.

Systemic oestrogen can be prescribed as an oral medication or as a transdermal preparation in the form of a spray, gel or patch. Low dose vaginal oestrogen can be prescribed as a cream, pessary or vaginal tablet.

When the endometrial tissue is exposed to estrogen alone, the risk of endometrial hyperplasia or cancer increases. For women who have undergone hysterectomy, they may be able to take oestrogen on its own. However, women who have not undergone hysterectomy will need to be prescribed a progestogen - in addition to oestrogen- to prevent endometrial overgrowth.

Again, there are different routes of administration and patient goals and preference should be taken into account. The LNG-containing IUS can provide endometrial protection for up to 5 years while also improving bleeding profile and providing convenient, effective contraception.

There are many different other progestogens available. Both dydrogesterone (Duphaston) and micronized progesterone (Utrogestan) are considered to have a safer profile than medoxyprogesterone, as they have lower impact on mammography breast density and a lower risk of VTE.

The oestrogen component of HRT should be continuous. The patch is changed twice per week, the gel and sprays are daily applications.

For women who have had a period in the last 12 months, they can be prescribed "cyclical" or "sequential" progestogen (ie it is usually prescribed to be taken for 14 consecutive days per month). They may continue to have some regular bleeding with this regimen. Women who are postmenopausal and have had 12 full months without menstruation, can be prescribed "continuous" progestogen, to take every day.

For women who are postmenopausal, there is a combination patch, providing continuous progestin for endometrial protection and a 50mcg dose of estrogen.

What about choosing between transdermal and oral oestrogen? Oral oestrogen might be considered to be more convenient and is the most commonly prescribed route of oestrogen in Ireland.

Oral oestrogen has been shown to increase the risk of VTE but this is not seen with transdermal oestrogen. The absolute risk of VTE is low but data from the WHI and more recent meta-analysis show a definite increased risk of VTE with the oral form of oestrogen. This is possibly due to the first pass metabolism of oestrogen, promoting an increase in hepatic clotting factors.

Low doses of oral oestrogen may have less of an impact on VTE risk but RCT data are lacking. Of note, there is no evidence of any increased risk of VTE with low dose vaginal oestrogen.

When choosing a progestogen, it is important to note that there are large observational studies showing that the Mirena IUD, micronized progesterone and dydrogesterone are unlikely to have a significant impact on VTE risk when compared to other progestogens.

## Vaginal Atrophy – The Impact of Inflammation

Genitourinary symptoms of menopause are common and are often underacknowleged. The majority of women, almost 70%, will report symptoms which include vaginal dryness/ discomfort/ itch, painful sex, increased frequench of urination, recurrent UTI, stress or urge incontinence. I have had patients who avoided having routine cervical smear exams as the pain of a speculum exam is so off putting.

These symptoms occur due to the loss of oestradiol and the subsequent impact on the vaginal and surrounding tissue. The pH of the vagina increases in postmenopause which changes the microbiome and increases the number of E Coli and other uropathogens. The loss of collagen and decrease in glycogen production cause reduced elasticity of the vaginal tissue. The introitus or opening of the vagina becomes more fragile and thinner,

The urethral orifice, Skene's and Bartholin's ducts openings have the same surface of stratified nonkeratinised squamous epithelium as the vaginal introitus/ tissue. Prior to menopause, this epithelial layer is approximately 1mm thick. After the loss of oestrogenic stimulation, this surface layer becomes much thinner. There is loss of lubrication and for some women. a loss of sensation due to reduced vulval blood supply which contributes to painful intercourse.

On examination, there may be visible atrophy of the labia majora and vaginal introitus. The labia minora may flatten or recede. The vulvar and vaginal mucosa can appear shiny/ pale/ dry and if there is inflammation, it may appear reddened or have petechiae. The vaginal rugae usually disappear, the vaginal canal is shorter and the cervix can become flush with the vaginal wall. There also may be uretheral caruncle visible on exam.

The first step is to ask about and recognise these symptoms. In terms of management options, starting with over-the-counter vaginal lubricants and moisturisers is helpful. It is also recommended to avoid irritants including panty liners/ perfumed soap etc.

Local oestrogens, in the form of a vaginal tablet/ pessary/ cream can provide dramatic results and due to their low systemic absorption, are extremely safe. There is also a once daily DHEA pessary (which acts as a precurser to oestrogen formation in situ, in the vaginal cells) and Ospemfiene, an oral SERM, which produces an oestrogen-like effect in the vaginal tissue.

Transdermal oestrogen has other benefits; it has less of an impact on triglycerides, less impact on thyroxine binding globulin, sex hormone binding globulin (SHBG) and a lower impact on gallbladder disease than oral oestrogen. The increased production of SHBG can diminish circulating free testosterone levels and in some women this can translate to a reduction in their libido.

Dermal oestrogen also has the advantage of achieving a more steady state than oral. As a consequence, it may be the better option for women who suffer with migraine.

Generally speaking, you can start at the lowest dose and titrate upwards slowly until symptom relief is achieved.

We have observational data looking at coronary heart disease and menopausal hormone therapy, suggesting that there is a reduced risk of CHD in women who initiate hormone therapy when they are younger than 60 and within ten years of their last period. A Cochrane analysis in 2015 reported a significant reduction in cardiovascular events and all -cause mortality in women who had started their hormone therapy within ten years of their last menstrual period when compared to placebo.[3]

For women who initiate HRT outside of this window, the WHI long-term follow-up and also the Cochrane analysis did not suggest and significant increase in the risk of cardiovascular events.

Standard dose (50mcg patch or equivalent) estrogen therapy prevents bone loss in postmeno- pausal women by inhibiting osteoclast-driven bone resorption and a reduced rate of bone remodelling. Randomized, controlled trials and observational studies show that standard-dose hormone therapy also reduces postmenopausal fractures, including hip, spine, and all non-spine fractures, even in women without osteoporosis. The impact of estrogen on bone density is dose-related, the lower the dose, the lower the protection. The bone protection also dissipates rapidly after discontinuation of oestrogen.

All women who have had early or premature menopause (defined as a cessation of ovarian function under the age of 40, affecting 1% of women. Early menopause, under the age of 45, affects approximately 5% of women) require bone protection. Hormone therapy (rather than bone specific treatments) is likely their best option, until they reach the average age of menopause, when their treatment plan can be reassessed.

For women with vasomotor symptoms aged younger than 60 years or who are within 10 years of menopause onset, hormone therapy is probably the most appropriate bone-active therapy in the absence of contraindications.[4]

The impact of menopausal hormone therapy on breast cancer risk is complicated. Different types of oestrogen/ progestogen, as well as the dose, duration of use, timing of initiation, not to mention the patient's own characteristics and background risk, may play a role in the impact of hormone therapy on the breast.

From the WHI trial, we learned that compared with placebo, women who had conjugated equine oestrogen alone, had a reduction in breast cancer risk for up to ten years.

We know that increasing duration of use relates to increasing impact on breast cancer risk. The WHI (which involved the use of conjugated equine estrogen and medoxyprogesterone), reported an attributable risk of "less than 1 additional case of breast cancer diagnosed per 1,000 users annually,[5] a risk slightly greater than that observed with one daily glass of wine, less than with two daily glasses, and similar to the risk reported with obesity, low physical activity, and other medications". (as per the NAMS position statement, 2017)

The "E3N" study, in France, was the first to demonstrate that estrogen + micronized progesterone or oestrogen + dydrogesterone combinations may be the least harmful menopausal hormone therapies with respect to postmenopausal breast cancer risk.

It has been estimated that just under a quarter of breast cancer diagnoses in the UK may be preventable by minimizing modifiable risk factor exposure where the proportion of breast cancers attributable to HRT exposure is estimated to be the same as that associated with lack of exercise (i.e. 3%) and less than those attributed to alcohol (6%) or postmenopausal overweight and obesity (9%).[6]

Of note, observational evidence suggests that taking hormone therapy does not further alter the risk for breast cancer in women with a family history of breast cancer.

Family history is, of course, important and along with other known risk factors for breast cancer, be considered in the discussion.

When can I discontinue HRT? Women who have started their systemic hormone therapy within 10 years of their LMP and who have not developed new health risks, can safely continue their prescription for as long as their benefit outweighs their risk.

- Hormone therapy generally does not need to be routinely discontinued in women aged older than 60 years and can be considered for continuation beyond age 60 years for persistent vasomotor symptoms, QOL issues, or prevention of osteoporosis after appropriate evaluation and counselling of benefits and risks. Don't forget that 10-15% of women will have vasomotor symptoms that persist > 20 years. Not a pleasant thought.

  Having annual review and regular discussion, revising the risk and benefits is important. Keeping an eye on blood pressure and changing to potentially safer low-dose transdermal routes should also be considered.

- Vaginal oestrogen may be used at any age for prevention or treatment of vaginal dryness, painful sex or bladder symptoms related to menopause. The systemic absorption of low dose vaginal oestrogen is low that it can be considered in women who have had breast cancer and do not have adequate symptomatic relief using vaginal moisturizers.

Don't forget that there are alternative options available. SSRI, SNRI, Gabapentin, Clonidine have all been shown to be effective for VMS. It is important to discuss the indication for starting SSRI/ SNRI medication and to explain their impact on reducing hot flushes. SSRIs can interfere with Tamoxifen metabolization and SNRIs should be considered first line for this population.

Tibolone, a synthetic steroid pill can be taken once per day for postmenopausal women (with or without a uterus). It acts via metabolites on both estrogen and androgen receptors and does not need to be prescribed with a progestin.

It has a good bleeding and safety profile with low impact on breast density. It has been associated with an increased risk of stroke in women over the age of 60 when compared to placebo.

A quick note on testosterone's role in all of this; (and as per the International Menopause Society's recent position statement)

With the current data, the only evidence-based indication for prescribing testosterone in women is for low libido (or hypoactive sexual dysfunction disorder). Anecdotally, there may be some benefit of testosterone for mood, energy and cognitive function but more trials/ research is needed. Transdermal testosterone is what is recommended and it is important to keep testosterone concentrations in the physiologic female range. Measure a free androgen index 4-6 weeks after starting testosterone and every 6 months thereafter. Aim for an FAI < 5.

There needs to be shared decision making, based on evidence -based discussion which allows women to make informed decisions. We have a responsibility to tackle the misinformation that surrounds perimenopause and menopause. We need to empower women to discuss their long-term health goals, screening and quality of life.

Navigating menopausal symptoms is at times challenging, nuanced, individual but ultimately, highly rewarding.

**References availble upon request**

# AZYTER®

Eye drops solution - Azithromycin 1.5%

## The first 3 day ocular antibiotic treatment

**Treatment for Conjunctivitis**

**2 drops daily**

**Indicated for use in neonates**

**Preservative free**


ADVERSE EVENTS SHOULD BE REPORTED. REPORTING FORMS AND INFORMATION CAN BE FOUND AT WWW.HPRA.IE/HOMEPAGE/MEDICINES/SAFETY-INFORMATION/REPORTING-SUSPECTED-SIDE-EFFECTS.
ADVERSE EVENTS SHOULD ALSO BE REPORTED TO THEAPAMEX LIMITED 094 9250290 OR MEDICAL INFORMATION ON +44 345 521 1290

**AZYTER 15 mg/g, EYE DROPS SOLUTION in single-dose container**

**Prescribing Information:** Please refer to Summary of Product Characteristics before prescribing. Additional information available on request.
**Presentation and active ingredients:** Azithromycin 15 mg/g eye drops solution. Single dose container, each containing 0.25g, enclosed in a sachet. Box of six single dose containers.
**Indications, Dosage and Administration:** Local antibacterial treatment of conjunctivitis caused by susceptible strains: - Purulent bacterial conjunctivitis, - Trachomatous conjunctivitis caused by Chlamydia trachomatis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Adults, Elderly, Children (birth to 17 years): one drop in the conjunctival fornix twice a day, morning and evening, for three days only. Adhere to the dosing regimen for successful treatment.
**Contraindications, Precautions and Warnings:** Contraindicated in hypersensitivity to azithromycin, other macrolides or the excipients. In the event of an allergic reaction, discontinue treatment. Do not inject or swallow and do not use for peri- or intra-ocular injection. In neonates, non-trachomatous conjunctivitis caused by Chlamydia trachomatis and conjunctivitis caused by Neisseria gonorrhoeae require a systemic treatment. In neonates and infants below the age of 3 months systemic infection due to Chlamydia trachomatis may accompany conjunctivitis. In case of suspicion, systemic treatment is required. Do not use as a prophylactic treatment of bacterial conjunctivitis in newborn infants. Do not continue to instil the eye drops after the end of treatment on the third day, even if residual signs of bacterial conjunctivitis remain. Symptomatic relief occurs generally within 3 days. If there are no signs of improvement after 3 days, diagnosis should be reconsidered. Contact lenses should not be worn by patients with bacterial conjunctivitis. Rare serious allergic reactions, including angioneurotic oedema and anaphylaxis, dermatologic reactions including acute generalised exanthematous pustulosis (AGEP), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. Some of these have resulted in recurrent symptoms, including when symptomatic therapy is discontinued, and required a longer period of observation and treatment. In concomitant treatment with another eye drops, allow 15 minutes between instillation of the two solutions and instil Azyter last.
**Interactions:** None expected with the use of the of the eye drops solution.
**Driving and using machines:** If vision is blurred after instillation, do not drive or use machines until normal vision has returned.
**Fertility, pregnancy and lactation:** No effect on fertility is anticipated. Azyter can be used during pregnancy and breast feeding. **Undesirable Effects:** Immune system disorders Uncommonly - Angioedema, hypersensitivity. Eye disorders Very commonly - ocular discomfort (pruritus, burning, stinging) on instillation. Commonly - blurred vision, sticky eye sensation, foreign body sensation on instillation. Uncommonly -Conjunctivitis, allergic conjunctivitis, keratitis, eczema eyelids, eyelid oedema, eye allergy, conjunctival hyperemia, lacrimation increased upon instillation, erythema of the eyelid. Skin and subcutaneous tissue disorders Not known (cannot be estimated) - Toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson syndrome, dermatitis exfoliative, acute generalised exanthematous pustulosis (AGEP). Adverse events should be reported. Reporting forms and information can be found at **http://www.hpra.ie**
**Legal Category:** POM. **PA No:** PA1107/004/001
**Marketing Authorisation Holder:** Laboratoires Thea, 12 Rue Louis Blériot, 63017 Clermont-Ferrand Cedex 2, FRANCE.
**Date of Preparation:** September 2020.
**Item code:** TP20038

THEAPAMEX
let's open our eyes

TheaPamex Ltd., 14 Moneen Business Park, Castlebar, Co. Mayo
Phone: 094 925 0290

www.theapharma.ie

TP21009

# Conjunctivitis in Children: *The Pharmacy Role*

***Conjunctivitis, commonly referred to as pink eye, involves inflammation of the outer layer of the eye and inside of the eyelid. Common causes include viruses, bacteria, allergens, contact lenses, fungi, and certain diseases.***

Viral and bacterial conjunctivitis can spread quickly among young children in daycare and school settings but can also occur in adults. Pharmacists can play an important role in patient education.

Good vision is essential to learning. According to the Association of Optometrists Ireland, all children should have an eye examination with an optometrist as early as possible when they start school.

More and more customers are relying on their local pharmacy when it comes to minor ailments as has been increasingly difficult to visit their GP. As a result of this, patients will have gained a lot of trust in the pharmacy profession and should in future know to turn to their local pharmacist for advice before going to the doctor.

Pharmacists and pharmacy staff need to keep on top of training in areas such as eye health, especially in children and adolescents, so that they can be confident in their ability to recommend certain products and know when to refer on to a GP. This is essential for building up a good rapport with patients, ensuring they will return for your advice in future.

It is important that staff have the confidence to ask appropriate questions to establish the level of discomfort a patient is feeling, how long this issue has been occurring, other medications etc. This will help the staff to know whether they can recommend a product for this issue or whether they need to refer this customer to the pharmacist or the GP to ensure they get appropriate treatment. Any educational information available from the product manufacturers should be taken advantage of.

The key to preventing long term vision problems is early detection. Correcting a child's vision problem before the age of 7 can significantly reduce the risk of having a vision problem for life. If there is a family history of eye sight problems, if a child is having problems in school or parents are worried about their child's vision in any way, advise them to bring them along to their local optometrist and ask about an eye examination.

Always remember that undetected vision problems can cause learning and behavioural problems.

Signs that a child may have a problem with their vision include

- Complaining of not being able to see black/white board or TV
- The eye turning in or out
- Holding things too close to the face
- Frequent Headaches (esp in older children)
- Eye rubbing and blinking
- Reduced attention span at activities
- Avoidance of reading or close work
- Covering one eye or tilting the head
- Difficulty in reading, repeatedly losing place on page
- Poor memory retention of what has been read or studied

## Conjunctivitis

Conjunctivitis is the inflammation or infection of the conjunctiva, a thin translucent membrane that covers the anterior surface of the sclera and the inner surfaces of the eyelids. It acts as a physical barrier to prevent microbes from entering and works to lubricate the eye by secreting mucin from its goblet cells which form a part of the tear film. Conjunctivitis, depending on presenting symptoms can be either allergic or infective.

## Allergic Conjunctivitis (AC)

Allergic conjunctivitis can be seasonal or perennial and occurs when the eyes come into contact with an allergen such as pollen, animal dander or dust mites. Symptoms occur in both eyes and include generalised redness which extends to the inner surface of the eyelids. Other symptoms of AC include sore, itchy, watery eyes and swelling of the eyelids. Patients may experience associated symptoms of allergic rhinitis such as a runny or blocked nose and sneezing.

Treatment of AC typically involves the use of OTC eyedrops that contain either an antihistamine or a mast cell stabiliser. Antazoline, an antihistamine is found in combination with xylometazoline, a sympathomimetic that constricts the blood vessels to reduce redness. It is recommended for rapid relief of the initial symptoms of the allergic reaction but not

intended for use longer than seven days due to the risk of rebound hyperemia and is licensed for use in adults and children over 12 years.

Sodium cromoglicate, a mast cell stabiliser can be use prophylactically while exposed to the allergen. It does not provide rapid relief from the symptoms but can be effective at controlling symptoms over a longer period of time and is suitable for use in adults and children although data is limited to the recommended minimum age of use.

### Infective Conjunctivitis (IC)

Infective conjunctivitis, subdivided into bacterial and viral, usually affects both eyes but can begin in one with symptoms developing in the second eye within 24-48 hours. Causative bacteria include, S.aureus, S. pnuemoniae and H.influenzae and adenovirus accounts for a high percentage of cases of viral conjunctivitis.

Presenting symptoms can help to distinguish between the two but often times this can be difficult to do. A white-yellow mucopurulent discharge is typically present in bacterial conjunctivitis whereas with viral cases, the discharge tends to be watery. A gritty, sore feeling can be a symptom of both and lubricant eye drops can be used to help ease the discomfort. Sometimes in cases of viral conjunctivitis there may be associated cold-like symptoms such as a sore throat, temperature and a cough. Both types of infection are typically self-limiting but topical antibiotics have been shown to reduce duration of infection in bacterial conjunctivitis and can be prescribed if symptoms are not resolving or worsening.

At home management is important in easing symptoms and preventing further infection.

Patient's should be advised to:

- wash their hands thoroughly after any contact with the eyes
- use their own face cloths/towels
- avoid touching the eye with any eye drop preparation as this can contaminate the product and contribute to further spread of the infection.
- gently cleanse the eye with cotton wool soaked in cooled boiled water to remove sticky discharge.
- remove contact lenses until all signs and symptoms of infection have gone and for at least 24 hours after a course of topical antibiotics.

A patient should be referred to their doctor if their symptoms are not improving or they experience any of the following:

- true pain in the eye as opposed to a gritty feeling
- redness localised around the pupil
- photophobia and disturbed vision such as haloes around objects
- loss of/reduced vision

# News

## Shining a Light on Migraine

The Migraine Association of Ireland recently created a survey with the aim to gain an understanding of how the Covid-19 pandemic has affected migraine sufferers.


Dr Martin Ruttledge, Consultant Neurologist, Beaumont Hospital & Hermitage Medical Clinic

The survey shines a light on the impact that pandemic restrictions are having on migraine sufferers in Ireland.

Conducted to coincide with Migraine Awareness Week (September 6th – 12th), the survey was carried out online among 120 adults living with migraine in Ireland. The survey shows that 56% of respondents were getting more frequent migraines, with 69% of this group reporting their symptoms of migraine have become more severe since the pandemic began. 34% of respondents were in the 35-44 age group; 40% in the 45-54 age group and the remaining 26% in the 18-24 (3%), 25-34 (17%), and 55-65+ (6%) age group(s).

Of those respondents who said their migraine had become more frequent, over four-fifths, or 84%, said that this was due to stress caused by the COVID-19 pandemic. Other factors for triggering a moderate to severe increase in migraines included changes to their routine (67%), a lack of sleep (63%) and increased screen time (60%).

The survey also found that among the individuals who were experiencing more frequent migraines, over one-third (37%) were working from home, 21% said that their working hours had increased during the pandemic and 20% were no longer working.

A small number of respondents, 18%, reported a decrease in the frequency of their migraines since the introduction of the COVID-19 restrictions. Similarly, 13% of respondents reported a decrease in the severity of their migraines.

With regard to the availability of appointments with healthcare professionals, 52% of respondents to the survey said that their appointments were either cancelled or postponed since the start of the pandemic. almost half (49%) of all respondents who experienced an increase in migraines reported cancelled or postponed appointments.

While only 41% of all respondents have had a virtual health-related consultation since the pandemic began, most of this group (68%) rated their consultation as either 'good' or 'excellent'.

Dr Martin Ruttledge, Consultant Neurologist, Beaumont Hospital & Hermitage Medical Clinic said, "It's worrying that the survey shows that many migraine sufferers are either experiencing more severe or frequent migraines. However, it is not unexpected, as we know that stress is a very common exacerbating factor in this condition, and it has been a very stressful period for everybody over the last 4-5 months with the Covid pandemic. Migraine, especially the more chronic forms, can be a very disabling neurological disorder, and the worldwide uncertainty in recent months has only made the situation worse. Patients should seek advice from their primary care doctors and other healthcare professionals if they are struggling. We are still having face to face and virtual consultations in our migraine clinic, and many GP's are reviewing their patients regularly, both in person and by phone. There are effective treatments available for many migraine sufferers and we are still available for our patients."

# Effects of Lockdown on Health

New research from RCSI University of Medicine and Health Sciences and Children's Health Ireland (CHI) shows babies born during the earliest lockdown in 2020 had a very low rate of antibiotic use and reduced hospital admissions.

The research found that the babies had very low rates of Covid-19 infection by six months of age, suggesting lockdown was an effective public health strategy in protecting one of society's most vulnerable groups.

The CORAL study is collecting blood and stool samples from 360 babies to investigate the impact of Covid-19 lockdown on their coronavirus exposure and routine healthcare access in Ireland.

Principal investigator, Professor Jonathan Hourihane from CHI at Temple Street and RCSI's Department of Paediatrics, said, "We set up the study to see if lockdown might support the so-called hygiene hypothesis – suggesting that the way we live so cleanly nowadays increases allergy rates. Initial results of the study show very low rates of antibiotic use and reduced hospital admissions for our participants. We also saw higher than average rates of immunisation in babies when it was thought uptake would actually decline, due to fears about going to healthcare facilities."

In total, only four participating children contracted Covid-19 during the first six months – two who had positive tests in the community and two other babies having unexpectedly positive Covid-19 results when attending their appointments in CHI at Connolly.

Professor Hourihane added: "We will continue to study the stool microbiome and allergy rate results but the indication of low Covid infection rates, low antibiotic use and low hospital attendance suggest we are on the right track with fewer infections circulating. It is reassuring that this population of infants born during lockdown have received routine healthcare as normal."

# Expand Role of Pharmacy in Health Threats

Pharmacists must be allowed to do more to manage respiratory conditions in communities if the urgent need to address the harmful effects of air pollution on health is to be met, the International Pharmaceutical Federation (FIP) has said.

Catherine Duggan, FIP CEO

The expansion of pharmacists' roles in mitigating the health threats of air pollution is among several actions described in a call to action issued by FIP, marking the United Nations International Day of Clean Air for Blue Skies.

The call to action is based on priorities identified by a round table of experts organised by FIP in collaboration with The Clean Breathing Institute (TCBI) earlier this year. "Air pollution is one of the top 10 threats to global health, according to the World Health Organization, with harmful effects manifesting in cancer, stroke, allergies, chronic obstructive pulmonary disease (COPD) and asthma, among other serious conditions.

FIP believes that pharmacists, at the hearts of communities and uniquely positioned to triage and manage people with respiratory symptoms and diseases, have the potential to make a huge impact on health outcomes," said FIP CEO Catherine Duggan.

The FIP call to action recommends pharmacy services that identify and reduce risk factors, such as smoking cessation, education on nasal hygiene and optimisation of inhaler technique for patients with COPD or asthma, as well as services that screen for vaccine hesitancy and social vulnerability. However, the federation recognises that policies are needed in order to increase public awareness of air pollution and pharmacists' related roles, and to scale up pharmacy education in this field. Detailed measures are described in the call to action.

Recent findings of a survey by FIP and TCBI support a need for an expanded role for pharmacists in air pollution and respiratory health, and FIP has called for incentives to encourage these services to become mainstream practice.

"In this call to action, FIP has made clear its commitment to advocating air pollution reduction as a health measure and to supporting pharmacists and their national organisations to provide better respiratory primary healthcare services. Our profession must be mobilised to act on this important issue," Dr Duggan said.

September 6th-10th recently marked Clean Air Week, and FIP invited individual pharmacists to pledge their commitment to the key actions described in the FIP call to action.

Meanwhile, the Irish Heart Foundation has said strict new measures on the burning of solid fuels in homes will reduce the number of lives lost to dirty air.

The charity welcomed Department of the Environment, Climate and Communications regulations - which include a national ban on smoky fuels in 2022 - as a "huge step" in reducing the impact of toxic air pollution.

"Air pollution is responsible for over 1,300 deaths every year in Ireland, with the vast majority of these due to heart disease and stroke," said Mark Murphy, Advocacy Officer with the Irish Heart Foundation.

"These measures will have a significant impact on this largely preventable loss of life as well as improving overall levels of public health.

"There is simply no safe level of exposure to air pollution, and while these updated domestic solid fuel regulations still permit the burning of some solid fuel with stricter standards, they are a huge step in the right direction and will reduce the number of lives lost to dirty air."

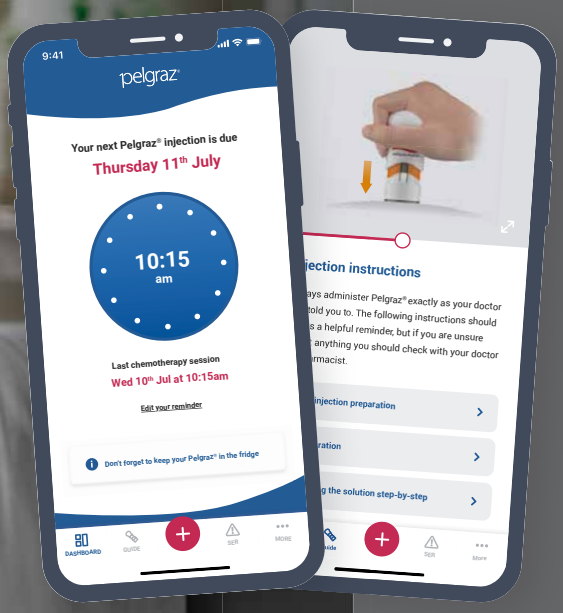
Mark Murphy, Irish Heart Foundation

Although the new measures will effectively ban and curtail the burning of smoky coal, wet wood and sod peat, the national heart and stroke charity said thousands of fuel-poverty households in Ireland still hugely reliant on these fuels, can not be left behind.

In its 2022 pre-budget submission, it calls for the introduction of a Green Transition Fuel Allowance to support and facilitate those most vulnerable in moving away from the worst affecting solid fuels to more sustainable and healthier forms of heating.

# Pelgraz® PFI Patient Support App

The Pelgraz® PFI App is designed to support patients **self-administering Pelgraz® PFI at home**




Download the Pelgraz® PFI App in the App store, or Google Play store, today

pelgraz® pegfilgrastim Pre-Filled Injector

GET IT ON Google Play

Download on the App Store

Use your smart phone to scan the QR code and be directed straight to the Pelgraz® PFI App

# Confidence, Convenience, Compliance

**ABBREVIATED PRESCRIBING INFORMATION**

Please refer to the Summary of Product Characteristics (SmPC) before prescribing **Pelgraz▼** (pegfilgrastim) **6 mg solution for injection in pre-filled syringe or pre-filled injector. Presentation:** Each pre-filled syringe or pre-filled injector contains 6 mg of pegfilgrastim* in 0.6 mL solution for injection. The concentration is 10 mg/mL based on protein only**. *Produced in *Escherichia coli* cells by recombinant DNA technology followed by conjugation with polyethylene glycol (PEG). **The concentration is 20 mg/mL if the PEG moiety is included. **Indications**: Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). **Dosage and Administration**: Pelgraz therapy should be initiated and supervised by physicians experienced in oncology and/or haematology. Posology: One 6 mg dose (a single pre-filled syringe or pre-filled injector) of Pelgraz is recommended for each chemotherapy cycle, given at least 24 hours after cytotoxic chemotherapy. Safety and efficacy of Pelgraz in children and adolescents has not yet been established and no recommendation on a posology can be made. No dose change is recommended in patients with renal impairment, including those with end-stage renal disease. **Method of administration:** Pelgraz is for subcutaneous use. The injections should be given subcutaneously into the thigh, abdomen or upper arm. See SmPC for instructions on handling of the medicinal product before administration. **Contraindications**: Hypersensitivity to pegfilgrastim or any of the excipients in Pelgraz. **Warnings and precautions**: To improve the traceability of biological medicinal products, the trade name of the administered product should be clearly recorded. The long-term effects of pegfilgrastim have not been established in acute myeloid leukaemia (AML); therefore, it should be used with caution in this patient population. Granulocyte-colony stimulating factor (G-CSF) can promote growth of myeloid cells *in vitro* and similar effects may be seen on some non-myeloid cells *in vitro*. The safety and efficacy of pegfilgrastim have not been investigated in patients with myelodysplastic syndrome, chronic myelogenous leukaemia, and in patients with secondary AML; therefore, it should not be used in such patients. Particular care should be taken to distinguish the diagnosis of blast transformation of chronic myeloid leukaemia from AML. The safety and efficacy of pegfilgrastim administration in *de novo* AML patients aged < 55 years with cytogenetics t(15;17) have not been established. The safety and efficacy of pegfilgrastim have not been investigated in patients receiving high dose chemotherapy. This medicinal product should not be used to increase the dose of cytotoxic chemotherapy beyond established dose regimens. Pulmonary adverse reactions, in particular interstitial pneumonia, have been reported after G-CSF administration. Patients with a recent history of pulmonary infiltrates or pneumonia may be at higher risk. The onset of pulmonary signs such as cough, fever, and dyspnoea in association with radiological signs of pulmonary infiltrates, and deterioration in pulmonary function along with increased neutrophil count may be preliminary signs of adult respiratory distress syndrome (ARDS). In such circumstances pegfilgrastim should be discontinued at the discretion of the physician and the appropriate treatment given. Glomerulonephritis has been reported in patients receiving filgrastim and pegfilgrastim. Generally, glomerulonephritis resolved after dose reduction or withdrawal of filgrastim and pegfilgrastim. Urinalysis monitoring is recommended. Capillary leak syndrome has been reported after G-CSF administration and is characterised by hypotension, hypoalbuminaemia, oedema and haemoconcentration. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care. Generally asymptomatic cases of splenomegaly and cases of splenic rupture, including some fatal cases, have been reported following administration of pegfilgrastim. Spleen size should be carefully monitored (e.g. clinical examination, ultrasound). A diagnosis of splenic rupture should be considered in patients reporting left upper abdominal pain or shoulder tip pain. Treatment with pegfilgrastim alone does not preclude thrombocytopenia and anaemia because full dose myelosuppressive chemotherapy is maintained on the prescribed schedule. Regular monitoring of platelet count and haematocrit is recommended. Special care should be taken when administering single or combination chemotherapeutic medicinal products which are known to cause severe thrombocytopenia. Pegfilgrastim in conjunction with chemotherapy and/or radiotherapy has been associated with development of myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) in breast and lung cancer patients. Patients treated in these settings should be monitored for signs and symptoms of MDS/AML. Sickle cell crises have been associated with the use of pegfilgrastim in patients with sickle cell trait or sickle cell disease. Therefore, use caution when prescribing pegfilgrastim in patients with sickle cell trait or sickle cell disease, monitor appropriate clinical parameters and laboratory status and be attentive to the possible association of this medicinal product with splenic enlargement and vasoocclusive crisis. White blood cell (WBC) counts of $100 \times 10^9$/L or greater have been observed in less than 1% of patients receiving pegfilgrastim. No adverse reactions directly attributable to this degree of leukocytosis have been reported. Such elevation in WBCs is transient, typically seen 24 to 48 hours after administration and is consistent with the pharmacodynamic effects of this medicinal product. Consistent with the clinical effects and the potential for leukocytosis, a WBC count should be performed at regular intervals during therapy. If leukocyte counts exceed $50 \times 10^9$/L after the expected nadir, this medicinal product should be discontinued immediately. Hypersensitivity, including anaphylactic reactions, have been reported with pegfilgrastim. Permanently discontinue pegfilgrastim in patients with clinically significant hypersensitivity. Do not administer pegfilgrastim to patients with a history of hypersensitivity to pegfilgrastim or filgrastim. If a serious allergic reaction occurs, appropriate therapy should be administered, with close patient follow-up over several days. Stevens-Johnson syndrome (SJS), which can be life-threatening or fatal, has been reported rarely in association with pegfilgrastim treatment. If the patient has developed SJS with the use of pegfilgrastim, treatment must not be restarted at any time. As with all therapeutic proteins, there is a potential for immunogenicity. Rates of generation of antibodies against pegfilgrastim is generally low. Binding antibodies do occur as expected with all biologics; however, they have not been associated with neutralising activity at present. Aortitis has been reported after filgrastim or pegfilgrastim administration in healthy subjects and in cancer patients. The symptoms experienced included fever, abdominal pain, malaise, back pain and increased inflammatory markers (e.g. C-reactive protein and WBC count). In most cases aortitis was diagnosed by CT scan and generally resolved after withdrawal of filgrastim or pegfilgrastim. The safety and efficacy of Pelgraz for the mobilisation of blood progenitor cells in patients or healthy donors has not been adequately evaluated. Increased haematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone-imaging findings. This should be considered when interpreting bone-imaging results. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. Pelgraz contains less than 1 mmol sodium (23 mg) per 6 mg dose, that is to say essentially 'sodium-free'. The needle cover contains dry natural rubber (a derivative of latex), which may cause allergic reactions. **Pregnancy and Lactation**: Pegfilgrastim is not recommended during pregnancy and in women of childbearing potential not using contraception. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from pegfilgrastim therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. **Adverse Events include: Adverse events which could be considered serious include: Common:** Thrombocytopenia. **Uncommon:** Myelodysplastic syndrome, acute myeloid leukaemia, sickle cell anaemia with crisis, capillary leak syndrome, glomerulonephritis, hypersensitivity reactions (including angioedema, dyspnoea, anaphylaxis), splenic rupture (including some fatal cases), Sweet's syndrome (acute febrile neutrophilic dermatosis), pulmonary adverse reactions including interstitial pneumonia, pulmonary oedema and pulmonary fibrosis have been reported. Uncommonly cases have resulted in respiratory failure or ARDS which may be fatal. **Rare:** Aortitis, pulmonary haemorrhage, Stevens-Johnson syndrome. **Other Very Common adverse events:** Headache, nausea, bone pain. **Other Common adverse events:** Leukocytosis, musculoskeletal pain (myalgia, arthralgia, pain in extremity, back pain, musculoskeletal pain, neck pain), injection site pain, non-cardiac chest pain. See SmPC for details of other adverse events. **Shelf Life:** 3 years. Store in a refrigerator (2∞C – 8∞C). Pelgraz may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 72 hours. Pelgraz left at room temperature for more than 72 hours should be discarded. Do not freeze. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect the stability of Pelgraz. Keep the container in the outer carton in order to protect from light. **Pack Size:** One prefilled syringe or prefilled syringe injector with one alcohol swab, in a blistered packaging. **Marketing Authorisation Numbers: Pre-filled syringe:** EU/1/18/1313/001, **Pre-filled injector:** EU/1/18/1313/002. **Marketing Authorisation Holder (MAH):** Accord Healthcare S.L.U, World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6a planta, Barcelona, 08039 Spain. **Legal Category:** POM. Full prescribing information including the SmPC is available on request from Accord Healthcare Ireland Ltd, Euro House, Little Island, Co. Cork, Tel: 021-4619040 or www.accord-healthcare.ie/products. **Adverse reactions can be reported to Medical Information at Accord Healthcare Ltd. via E-mail:** medinfo@accord-healthcare.com **or Tel:** +44(0)1271385257.
**Date of Generation of API:** May 2021. IE-01426

accord
www.accord-healthcare.ie

medicines for ireland

Associated member of: medicines for europe better access. better health.

accord Oncology & Haematology

**Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie), or by e-mailing medsafety@hpra.ie. Adverse events should also be reported to Medical Information via email; medinfo@accord-healthcare.com or tel:0044 (0) 1271 385257**

July 2021. IE-01663

Continuing Professional Development

CPD

**AUTHOR: Donna Cosgrove PhD MPSI**

Donna graduated with a BSc in Pharmacy from the Royal College of Surgeons in Ireland. She then returned to university to complete a MSc in Neuropharmacology. This led to a PhD investigating the genetics of schizophrenia, followed by a postdoctoral research position in the same area. Currently Donna works as a pharmacist in Galway, and as a clinical writer.

## 60 Second Summary

During the first two to three days of life, it is common for full term infants lose weight. It is important to recognise normal weight loss and gain patterns in order to put early feeding difficulties in context. In the first five to seven days, infants lose up to 10 per cent of birthweight, although this weight loss usually stops after about 3 or 4 days of life, and the majority of infants have returned to their birth weight by 3 weeks of age.

Infants develop at different stages, so solids should be introduced when the individual infant is ready - usually around 6 months. For a premature baby (born before 37 weeks) food should be introduced sometime between their 'corrected age' 4 and 6 months.

Usually people start with spoon feeding at four to six months of age, but by twelve months, the infant will be able to enjoy family meals. The vast majority of foods are suitable for infants as long as they are prepared appropriately.

Current World Health Organisation guidance, as well as the more local HSE guidance recommend that infants are initially offered smoothly blended foods, progressing in texture, until at 12 months, infants should be eating family foods.

Food, particularly that has round/spherical shapes, should be cut before offering to an infant or toddler, e.g. grapes, cherry tomatoes. Items like popcorn, marshmallows and hard sweets are a choking hazard so are best avoided until the child is about 5 years of age.

Pre- and postnatal flavour experiences can affect liking of flavours at weaning in infants. A research group in Philadelphia found that babies of pregnant and breastfeeding women who drank carrot juice were more likely to eat carrot-flavoured cereal than infants of women who did not.

**1. REFLECT -** Before reading this module, consider the following: Will this clinical area be relevant to my practice?

**2. IDENTIFY -** If the answer is no, I may still be interested in the area but the article may not contribute towards my continuing professional development (CPD). If the answer is yes, I should identify any knowledge gaps in the clinical area.

**3. PLAN -** If I have identified a knowledge gap - will this article satisfy those needs - or will more reading be required?

**4. EVALUATE -** Did this article meet my learning needs - and how has my practise changed as a result?Have I identified further learning needs?

**5. WHAT NEXT -** At this time you may like to record your learning for future use or assessment. Follow the 4 previous steps, log and record your findings.

Published by IPN. Copies can be downloaded from www.irishpharmacytraining.ie



# A-Z of Infant Nutrition

### Introduction

During the first two to three days of life, it is common for full term infants lose weight. It is important to recognise normal weight loss and gain patterns in order to put early feeding difficulties in context. In the first five to seven days, infants lose up to 10 per cent of birthweight, although this weight loss usually stops after about 3 or 4 days of life, and the majority of infants have returned to their birth weight by 3 weeks of age[1].

Feeding in the first 2 years of a child's life are particularly important: research has shown that adequate nutrition during this time decreases morbidity and mortality, reduces the risk of chronic disease, and contributes to optimal development[2,3]. Breast milk, when it is the sole source of nutrition for infants in the first six months of life, plays a critical role in development. WHO and UNICEF recommend[2]:

- Early initiation of breastfeeding (within 1 hour of birth)
- Exclusive breastfeeding for the first 6 months of life
- Introduction of nutritionally adequate and safe solid foods at 6 months together with continued breastfeeding up to 2 years of age or beyond.

However, only about 36% of infants aged 0–6 months worldwide were exclusively breastfed over the period of 2007-2014.

Human breast milk contains many compounds as well as living cells, hormones, active enzymes, immunoglobulins, and a additional bioactive compounds. These unique nutrients in breast milk cannot all be included in infant formulas, and as a result formula composition cannot exactly match human milk. Furthermore, some nutrients in human milk vary not only from the beginning to the end of each feed, but also between the stages of lactation, and as a result of different maternal diets[4]. The actual impact of these nutritional variations is not fully understood, as specific roles in affecting nutritional outcomes have not been determined. Research into the benefits of breastfeeding is still needed to distinguish which factors in human milk are most beneficial, but also to determine how much of the beneficial effect arises from breast milk ingestion as opposed to the act of breastfeeding itself[3]. There is compelling scientific evidence to support the association between breastfeeding and reduced risk of some illnesses e.g. gastrointestinal infections; however, it has been suggested that some links between breast feeding and other desirable outcomes are from studies that do not control adequately for confounding variables, leading to biased results[4, 5]. There are many women who do not breast feed, some who choose not to and some who are unable to, for a range of different reasons. In these situations the importance of sound knowledge, insight and high ethical awareness for healthcare workers has been identified by a Norwegian study on the experience of not breastfeeding in a predominantly breastfeeding culture[6]. The care and education of a mother and formula fed infant should be of a high standard even if formula feeding is not the preferred choice for the healthcare worker.

### Weaning

Infants develop at different stages, so solids should be introduced when the individual infant is ready - usually around 6 months. For a premature baby (born before 37 weeks) food should be introduced sometime between their 'corrected age' 4 and 6 months[7]. A small amount of food should be offered initially, and increased gradually as the child gets older, along with gradually introducing variety in food and texture. The number of times that the child is fed should be increased from e.g. 2 to 3 meals per day for infants aged 6 to 8 months of age to 3 to 4 meals per day for infants 9 to 23 months of age (with 1 to 2 additional snacks as required).

Babies should not be given solid foods before 17 weeks (4 months) because[7]:

- Their kidneys are not mature enough to handle food and drinks other than milk
- Their digestive systems are not yet developed enough to cope with solid foods

- Breast milk or formula milk is enough to meet nutritional needs until 6 months old
- Introducing other foods or fluids can displace the essential nutrients supplied by breast or formula milk
- Introducing solids too early can increase the risk of obesity in later life
- It can increase their risk of allergy

Waiting until after 26 weeks (6 months) is not recommended because:

- The infant's energy needs can no longer be met by either breast milk or formula milk alone
- Iron stores from birth are used up by 6 months and their iron needs can no longer be met by milk alone
- It delays their opportunity to learn important skills, e.g. self-feeding
- Introducing different textures stimulates the development of muscles involved in speech

The baby will show certain signs that they are ready to start on solid food, such as:

- Sitting up without support and being able to control head movements
- Not appearing to be satisfied after their milk feed
- Increased frequency and demand for milk
- Showing an interest in food/ reaching out for food
- Watching people eating with interest
- Chewing and dribbling (although this may be a sign of teething)

Usually people start with spoon feeding at four to six months of age, but by twelve months, the infant will be able to enjoy family meals. The vast majority of foods are suitable for infants as long as they are prepared appropriately. However, foods to avoid under 12 months are raw shellfish (as this can cause food poisoning); swordfish, shark, marlin or fresh tuna (these may contain high levels of mercury); unpasteurised dairy products; undercooked eggs, sugar, tea or coffee, liver, and processed or cured meats like ham, bacon or sausage. Babies should not be given foods that contain added salt, e.g. gravy, jars or packet sauces, stock cubes; because their kidneys are still developing (although baby-friendly stock cubes are available). Honey is not suitable until the infant is over 12 months due to the potential for it to carry bacterial spores.

From about 6 months of age, the HSE recommends[8] starting with food in the form of thin purées (Stage 1). This allows the infant to learn how to take food from a spoon, move it to the back of the mouth and swallow. From 6 to 9 months (Stage 2), thicker purées are recommended, progressing to smooth mashed foods, and mashed food with lumps. The infant will learn how to chew lumps, and may start to feed themselves small bite size pieces of food. During this stage, the baby should also be offered a cup or beaker of water to drink. Between 9 and 12 months of age (Stage 3), the baby can try lumpier textures, harder finger foods, drinking from a cup, and may attempt eating with a spoon themselves. This getting used to lumpy textures can also help with muscle and speech development. The HSE website provides more specific recommendations of particular foods that are suitable at each of these stages, and The FSAI provide sample meal planners for Stages 2 and 3[10]. If the infant is breastfed or taking less than 300mls of infant formula a day, 5 micrograms of vitamin D3 should be given every day from birth to 12 months. If the baby is fed more than this, they do not need a supplement.

By the time infants are between 9 – 12 months of age, milk intake should decrease to about 3 milk feeds (maximum 600mls milk if not breastfed) per day. If an infant is drinking more than this, or in excess of requirements, it can be useful for the parent or caregiver to space out milk feeds and meals and offer food before milk at mealtimes. Increasing the amount of food offered to 3 nutritious meals and 2-3 small snacks per day may help decrease milk requirements. To maintain hydration, cooled boiled water should be offered.

In the 1990s, it was thought that avoidance of allergenic foods in pregnancy, breastfeeding, and even until the infant is 12 months old could help prevent the onset of allergic diseases in infants with atopy in first degree relatives[11]. However, even when typical allergens were being avoided, the rate of food allergies (FA) in childhood continued to increase in Western countries, with delayed exposure even potentially increasing FA frequency. Consequently, updated guidelines changed previous recommendations, recognising that there was no evidence that a delayed introduction was useful for the primary prevention of FA. Gluten can be introduced gradually from four months of age. Other potential allergens such as peanuts (as a smooth spread), dairy, eggs and fish can be introduced from 6 months.

**Baby-Led Weaning**

Current World Health Organisation guidance, as well as the more local HSE guidance (above) recommend that infants are initially offered smoothly blended foods, progressing in texture, until at 12 months, infants should be eating family foods. Over the last 10–20 years, an alternative approach known as 'baby-led weaning' (BLW) has grown in popularity[12]. This involves allowing infants to self-feed family foods, encouraging the infant to set the pace and intake of the meal. Proponents of the BLW believe it promotes healthy eating behaviour and weight gain. It is still not generally considered in guidelines for new parents, partly as a result of an emerging but small evidence base. In reality this approach is likely what mothers did for millennia before the introduction of specially prepared foods. This increase in BLW may be due at least partly to the WHO increasing the age recommendation at which solid food is offered from four months to six months: the majority of infants of around 6 months have developed the skills needed

Figure 1. Positions to aid a choking infant[10]

to self-feed, including being able to sit up unsupported, bring food to their mouth, chew and swallow food. Few infants at 4 months old would be able to do this, meaning that puréeing and spoon-feeding was a necessity.

Some parents try a combination of baby-led weaning and spoon feeds. This can work well, particularly if your baby is less independent in their eating. It can ensure that they eat well and get all the nutrients they need[7]. It is important to allow infants to make a mess while learning to become independent feeders.

Concerns are often raised about the safety of BLW, particularly with respect to potential choking risk. In one study[13], authors compared the results of a survey taken by mothers of infants. They were grouped into mothers and infants who used the traditional weaning method, those who used BLW, and those who used a loose BLW approach, or a mixture of both. In total, 11.9% of the strict BLW group, 15.5% of the loose BLW approach and 11.6% of the traditional group had ever choked. Although the authors point out several limitations in the study, they suggest that these results support to the safety of the baby-led approach in terms of choking risk compared to traditional weaning.

**Choking Risk**

Food, particularly that has round/spherical shapes, should be cut before offering to an infant or toddler, e.g. grapes, cherry tomatoes. Items like popcorn, marshmallows and hard sweets are a choking hazard so are best avoided until the child is about 5 years of age.

Children under the age of three are at the highest risk of choking due to the small size of their respiratory tract. A baby should never be left unsupervised during food intake due to the risk of choking. Choking occurs when the airway suddenly becomes fully or partially blocked and interrupts breathing. An infant who is choking will be distressed and may be unable to cry, cough or breathe.

The following instructions should be used when advising parents/carers in case of infant choking[10]:

1. Lie the infant face down along your forearm or thigh with their head lower than their body. Support their head, jaw and neck
2. Give up to five firm slaps to the infant's back between the shoulder blades with the heel of your hand (the heel is between the palm of your hand and your wrist)
3. Check if the blockage has cleared. Look inside the infant's mouth and remove any obvious blockage. Do not poke your fingers into the infant's mouth unless you can see and reach the blockage. You may push it further in
4. If the airway is still blocked lay the infant along your forearm on their back with their head low, supporting their back and head, and give up to five chest thrusts. Chest thrusts can be performed by placing two fingers over the lower half of the infant's breastbone, below an imaginary line between the nipples. Using two fingers, push inwards and upwards (towards the head) against the infant's breastbone, one finger's breadth below the nipple line
5. Check if the blockage has cleared after each thrust, by looking inside the infant's mouth and removing any obvious blockage. Do not poke your fingers into the baby's mouth unless you can see and reach the blockage as you may push it further in
6. Keep doing 5 back blows and 5 chest thrusts until the object pops out and the infant begins to breathe again
7. If the infant becomes unresponsive, call for help and send someone to dial 999 or 112.

**Colic**

Colic is usually defined as crying for at least three hours per day, on at least three days per week, for at least three weeks. The definitive cause of colic is still unclear although trapped wind is what appears to cause most of the symptoms. A Cochrane review evaluated the effects of dietary modifications for colicky infants versus another intervention or placebo, with duration of crying or frequency of crying episodes reported as the main outcome[14]. Some studies reported beneficial effects supporting certain interventions, but due to overall small sample sizes and poor quality of the studies, the authors do not recommend any of dietary modifications assessed in the review. A second Cochrane review found that, although probiotics made little or no difference to the occurrence of infantile colic, they appeared to reduce crying time[15]. Cow's milk protein allergy (CMPA) should be considered if symptoms persist. If CMPA is suspected, a diary of feeds (even if exclusively breastfeeding) and symptoms is useful to help with diagnosis. Pharmacists are in a position to reassure parents that there are alternative hypoallergenic milk substitutes available if their infant is diagnosed with CMPA. Studies suggest that most children with CMPA will be milk tolerant by the age of three (non-IgE-mediated CMPA) and five years (IgE-mediated). Different "extensively hydrolysed formulas" (with the protein constituent already partially broken down) are available. These are either whey based (containing lactose) e.g. Aptamil Pepti; or casein based (gluten and lactose free) e.g. Nutramigen LGG. Amino acid formulations are also available e.g. Neocate LCP.

**Introducing Flavours to Infants**

Pre- and postnatal flavour experiences can affect liking of flavours at weaning in infants. A research group in Philadelphia found that babies of pregnant and breastfeeding women who drank carrot juice were more likely to eat carrot-flavoured cereal than infants of women who did not[16]. Similarly, when mothers ate fruits or vegetables, leading to infants experiencing the flavours in amniotic fluid and then mother's milk, this increased the palatability of these foods for the infant.

A systematic review[17] performed by the same research group concluded that there is limited but consistent evidence to indicate that flavours contained in foods and drinks in the maternal diet during pregnancy can transfer to and flavour amniotic fluid, and that foetal exposure to these flavours increases acceptance of the exposed flavour during infancy and potentially during childhood. Studies have shown that flavour transfer to amniotic fluid takes place after pregnant women ingest alcohol, anise, carrot, or garlic, although these findings may not be generalisable to all foods in the maternal diet during pregnancy. There is also evidence that flavour transfer to breast milk occurs after ingestion of alcohol, anise, caraway, carrots, eucalyptus, garlic, or mint.

Repeated dietary exposure to a fruit or vegetable also increases

the likelihood of the infant eating it. Infants repeatedly exposed to different vegetables on alternate days ate more of not only the vegetables to which they were exposed, but also novel vegetables. It can take up to 10-15 tries for a child to accept a new food so persistence can pay off! Children older than infants can continue to learn to like foods, but it is more difficult as they grow older.

**References**

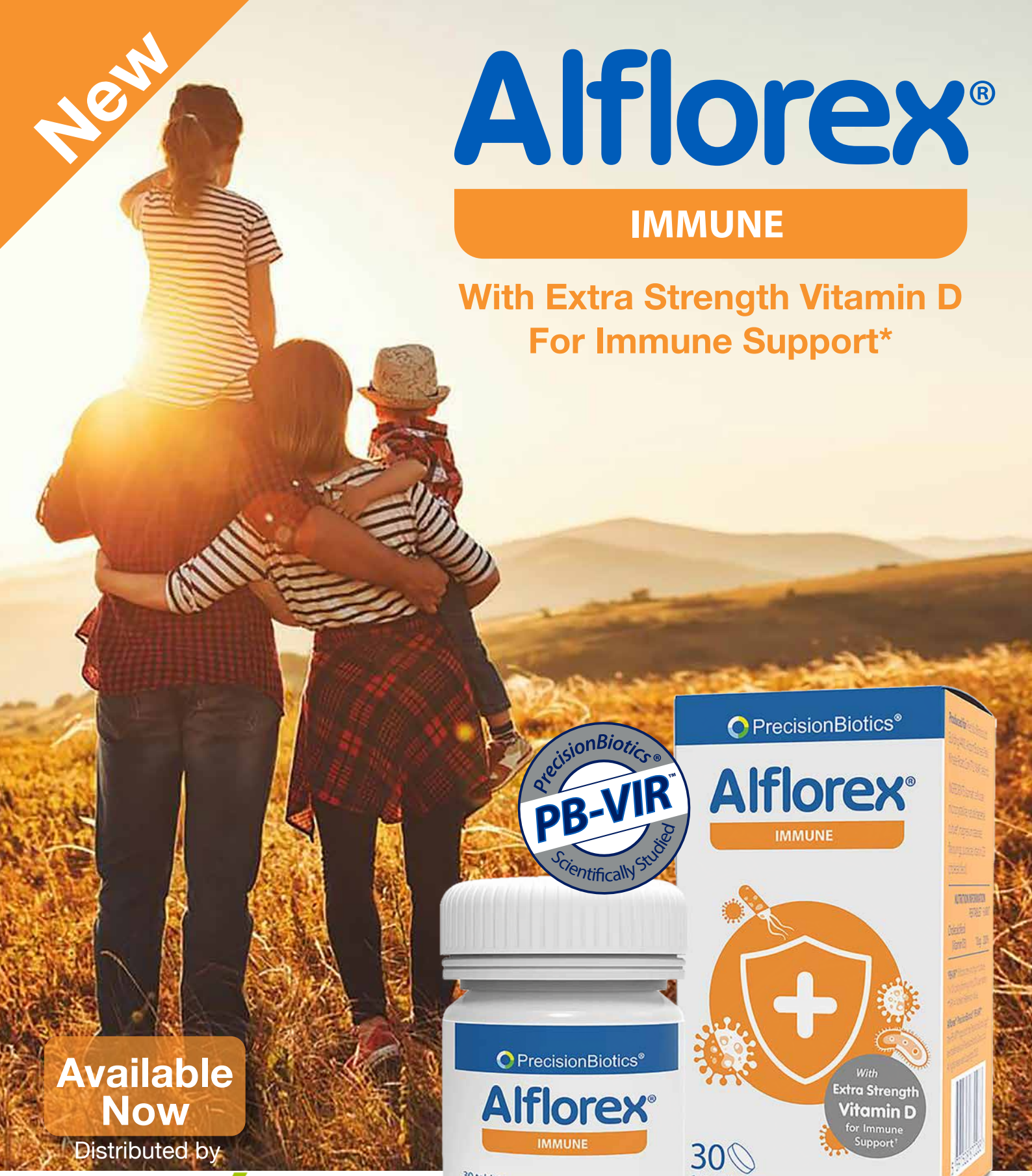

1. National Institute for Health Care and Clinical Excellence. (2017). Faltering growth: recognition and management of faltering growth in children [NG 75]. Available https://www.nice.org.uk/guidance/ng75/chapter/recommendation1s
2. World Health Organisation. (2018). Infant and Young Child Feeding. Retrieved from https://www.who.int/en/news-room/fact-sheets/detail/infant-and-young-child-feeding
3. Health Service Executive (2018). Weaning. Available https://www2.hse.ie/wellbeing/child-health/weaning/baby-led-weaning.html
4. Ryan, A. S., & Hay, W. W. (2015). Challenges of infant nutrition research: a commentary. Nutrition journal, 15(1), 42. Retrieved from https://nutritionj.biomedcentral.com/articles/10.1186/s12937-016-0162-0
5. Wolf, J. B. (2010). Is breast best?: Taking on the breastfeeding experts and the new high stakes of motherhood (Vol. 4). Nyu Press.
6. Oster, E. (2013). Expecting Better: Why the Conventional Pregnancy Wisdom is Wrong--and what You Really Need to Know (Vol. 1). Penguin.
7. Hvatum, I., & Glavin, K. (2017). Mothers' experience of not breastfeeding in a breastfeeding culture. Journal of clinical nursing, 26(19-20), 3144-3155.
8. Health Service Executive. (2018). Weaning - starting your baby on solid foods. Retrieved from https://www2.hse.ie/wellbeing/child-health/weaning/weaning-starting-your-baby-on-solid-foods.html
9. Health Service Executive (2018). My Child: 0 – 2 Years. Available https://www2.hse.ie/file-library/child-health/my-child-0-to-2-years-book.pdf
10. The Food Safety Authority of Ireland (2012). Best Practice for Infant Feeding in Ireland. Available https://www.fsai.ie/publications_infant_feeding/
11. Caffarelli, C., Di Mauro, D., Mastrorilli, C., Bottau, P., Cipriani, F., & Ricci, G. (2018). Solid food introduction and the development of food allergies. Nutrients, 10(11), 1790.
12. Brown, A., Jones, S. W., & Rowan, H. (2017). Baby-led weaning: the evidence to date. Current nutrition reports, 6(2), 148-156. Available https://link.springer.com/article/10.1007/s13668-017-0201-2
13. Brown, A. (2018). No difference in self-reported frequency of choking between infants introduced to solid foods using a baby-led weaning or traditional spoon-feeding approach. Journal of Human Nutrition and Dietetics, 31(4), 496-504.
14. Gordon, M., Biagioli, E., Sorrenti, M., Lingua, C., Moja, L., Banks, S. S., ... & Savino, F. (2018). Dietary modifications for infantile colic. Cochrane Database of Systematic Reviews, (10). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011029.pub2/abstract
15. Ong, T. G., Gordon, M., Banks, S. S., Thomas, M. R., & Akobeng, A. K. (2019). Probiotics to prevent infantile colic. Cochrane Database of Systematic Reviews, (3). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012473.pub2/full
16. Mennella, J. A., Reiter, A. R., & Daniels, L. M. (2016). Vegetable and fruit acceptance during infancy: impact of ontogeny, genetics, and early experiences. Advances in nutrition, 7(1), 211S-219S. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4717875/
17. Spahn, J. M., Callahan, E. H., Spill, M. K., Wong, Y. P., Benjamin-Neelon, S. E., Birch, L., ... & Casavale, K. O. (2019). Influence of maternal diet on flavor transfer to amniotic fluid and breast milk and children's responses: a systematic review. The American journal of clinical nutrition, 109 (Supplement_1), 1003S-1026S.


New

# Alflorex®

## IMMUNE

**With Extra Strength Vitamin D**
**For Immune Support***




**Available Now**
Distributed by

PameX Limited
Your Sales Partner in Ireland

Contains the unique **PB-VIR™** culture, a PrecisionBiotics strain

*Vitamin D contributes to the normal function of the Immune System
More information available at **www.precisionbiotics.com**

# Breast milk Proven to Enhance Heart Performance

New research from RCSI University of Medicine and Health Sciences demonstrates the beneficial effect of breast milk consumption on cardiovascular health and early cardiovascular development in premature infants.

Professor Afif EL-Khuffash, Clinical Professor of Paediatrics at RCSI and Consultant Neonatologist at the Rotunda Hospital, Dublin

The study of 80 preterm infants is the first of its kind to show that preterm infants with higher exposure their mother's own milk had enhanced cardiac function at age one year, with values approaching those of healthy full-term infants.

The research was led by Professor Afif EL-Khuffash, Clinical Professor of Paediatrics at RCSI and Consultant Neonatologist at the Rotunda Hospital, Dublin, in collaboration with researchers at University of Oxford; Mount Sinai Hospital, Toronto; Northwestern University Feinberg School of Medicine; Washington University School of Medicine; and, Harvard Medical School.

Children and adults who are born preterm are at increased risk of cardiovascular disorders, including ischemic heart disease, heart failure, systemic and pulmonary hypertension, and are more likely to die as a result of cardiovascular disease. The hearts of young people born early are known to have unique traits such as reduced biventricular volume, shorter length, lower systolic and diastolic function and a disproportionate increase in muscle mass. This results in impaired heart function, which is significantly lower than that of healthy infants who are born at term. This dysfunction is detectable at hospital discharge and persists throughout their adolescence.

This study shows that exclusive breast milk consumption in the first months after birth is associated with a normalisation of some of these traits. Premature infants exposed to a high proportion of their mother's own milk during the first few week after delivery had greater left and right heart function and structure with lower lung pressures and enhanced right heart response to stress at one year of age compared to preterm infants who had a higher intake of formula, with all measures approaching those seen in term-born healthy children.

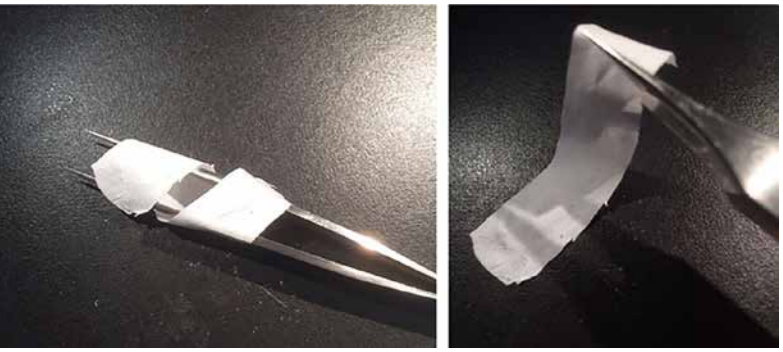
These findings were apparent before discharge from the hospital and persisted up to a year of age (the duration of follow up).

Professor EL-Khuffash said, "This study provides the first evidence of an association between early postnatal nutrition in preterm-born infants and heart function over the first year of age, and adds to the already known benefits of breast milk for infants born prematurely."

"Preterm infants have abnormal heart function. However, those who are fed their mother's own milk demonstrate recovery of their heart function to levels comparable to healthy term born infants. Preterm infants fed formula do not demonstrate this recovery."

# Switch On and Speed Up Healing

Researchers at CÚRAM, the SFI Research Centre for Medical Devices based at NUI Galway, have shown how the simple act of walking can power an implantable stimulator device to speed up treatment of musculoskeletal diseases.



CÚRAM Implantable Stimulator Device to treat tendon damage and disease. The image shows piezoelectric material spun into aligned nano-fibres to form a fine implantable mesh.

The results of have been published in the prestigious journal *Advanced Materials*.

The research establishes the engineering foundations for a new range of stimulator devices that enable control of musculoskeletal tissue regeneration to treat tendon damage and disease and sports injuries, without the use of drugs or external stimulation.

Lead researcher on the study, CÚRAM Investigator Dr Manus Biggs, said, "One of the most exciting parts of our study is that these implantable devices may be tailored to individual patients or disorders and may show promise in accelerating the repair of sport-related tendon injuries, particularly in athletes."

The study investigated whether electrical therapy, coupled with exercise, would show promise in treating tendon disease or ruptures. It showed that tendon cell function and repair can be controlled through electrical stimulation from an implantable device which is powered by body movement.

Dr Marc Fernandez, who carried out the principal research of the study at CÚRAM, said, "Successful treatment of tendon damage and disease represents a critical medical challenge.

"Our discovery shows that an electrical charge is produced in the treatment target area - the damaged or injured tendon - when the implanted device is stretched during walking. The potential gamechanger here is like a power switch in a cell - the electrical stimulus turns on tendon-specific regenerative processes in the damaged tendon."

# Calls for Greater Access to Health Information

The Citizens' Jury on Access to Health Information, led by the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), has published its deliberations, setting out six recommendations for policy-makers and expressing a strong preference for greater access to health information in Ireland.

After more than 12 hours of online deliberations, the 25 jurors concluded that citizens must be the owners of their own health data, and that practices, processes and policies developed to manage or share health information must be made in partnership with them. The jurors underline that health information must not only be easily accessible to every citizen who wants to view it, but that citizens must be able to actively manage, and consent to, the use of their information on an ongoing basis.

The jurors expressed a lack of trust in the State because of past failings in relation to health information collection and use. The jurors also spent time discussing the potential for data breaches, and they called for robust cybersecurity solutions and safeguards to protect their health information and a zero-tolerance approach to the misuse of health data.

**Recommendation Highlights**

Among the recommendations highlighted are:

- **Health Records:** health information should contain up-to-date, complete, joined-up data which provides an accurate and comprehensive account of the individual's history of contacts with the health service and his/her health record
- **Portal:** information sharing should be via a portal that is equally accessible to both the patient and the healthcare professionals engaged in their care
- **Closed Box:** information sharing should be limited, both in terms of what information can be viewed (closed box) and in terms of who can view the information (audit trail)
- **Citizen First:** health information must be first shared with every citizen who wants to view, and potentially control access to, their own health information
- **Public Champion:** health information sharing needs to be guided by an independent, State-mandated, public champion who acts in the interest of the citizen, and who is responsible for informing, educating, empowering, and protecting the public
- **Inappropriate Sharing:** health information should never be shared with employers, banks, or insurance, pension, and marketing companies
- **Price to Pay:** health information should not be given away 'for free', instead it should be treated as a modern-day 'national resource' from which society must accrue a tangible, financial benefit (or in-kind benefit) for sharing
- **Sanctions:** health information misuse should be approached from a position of zero-tolerance, especially misuse from within the system, in particular by public servants outside of healthcare professionals
- **Security:** health information must be appropriately secured by the State, and sufficient resources dedicated towards its security

Dr Derick Mitchell, CEO of IPPOSI, the Citizens' Jury said, "A Citizens' Jury on access to health information is very topical for a number of reasons – the initial rollout of the COVID-19 vaccine programme and the need to access records to identify priority groups; the subsequent development of a vaccine portal and the creation of the EU Digital COVID certificate; and, of course, the recent cyberattack on our national health system. People are worried about their data; they want to know who has it and who is in charge of protecting it but, more importantly, they want to play a central role in deciding what happens to it.

"Jurors expressed a clear desire for a connected, quality, digital health information system, and the need for accountability and independent oversight of our health information. Jurors also concluded that the sharing of health data for the improvement of patient care is a collective responsibility and ultimately the right thing to do – subject to the conditions set out.

"Our jurors have started the discussion, and we in IPPOSI believe it is up to the health policy-makers and decision-makers to take this further and start a national conversation about the future of our health information to deliver on this collective call for action.

# Infertility/Fertility

## *What Every Woman Should Know*

***Since 1970 the Billings Ovulation Method has been helping women manage their fertility naturally, using a simple method of proven effectiveness estimated to provide 80% of Natural Family Planning Worldwide.***

***Written by Billings Senior Teachers***

The Authentic Billings Ovulation Method has been scientifically researched and developed since 1953, is inexpensive, universally acceptable to all cultures, simple to learn and environmentally friendly.

It can be used at every stage of reproductive life allowing couples to plan their families naturally, it gives women insight into their own reproductive health allowing them to recognise any need to seek early and appropriate medical help.

It does not depend on temperature, calendar, chemical tests or calculations. It does not need regular periods. It can be used to achieve and to avoid pregnancy.

The combined fertility of the couple is central to use of the Billings Ovulation Method. In principle the male fertility does not vary, and the female fertility is cyclical.

Most women do not ovulate on the famous day 14; and many women have minor variations in the calendar length of their cycles. Also breastfeeding, weaning, recovery of cycles after pregnancy or hormonal contraception, weight gain, weight loss, athletic training, and stress alters many women's cycles temporarily. Helps Perimenopausal women as changes occur in their cycles as they traverse through the perimenopause.

So a method that follows the signs of a women's cycles day by day will not be misled by such variations.

It covers all stages and situations during a woman's reproductive years:

- Planning pregnancy
- Postponing pregnancy
- While Breastfeeding
- Post Pill (homonal contraception)
- Pre-Menopause
- Monitors Reproductive Health
- Can help with early diagnosis of
- Endometriosis/Polycystic Ovaries

The Billings Ovulation Method started by studying every indication of fertility/infertility, but rapidly settled on the sensation at the vulva as the best reflection of hormonal changes and potential fertility. Gradually this was supported by endocrine, ultrasound and physiological research, becoming refined until the current status, where a simply used method is taught by stringently qualified teachers.

**There are Four Phases of a Cycle**

- Menstruation
- BIP (BASIC INFERTILE PATTERN) Determines length of cycle (part of cycle that varies by days/weeks during breastfeeding)
- Fertile Phase leading to PEAK (ovulation)
- Luteal Phase (Infertile) From ovulation to next
- Menstruation (11 – 16 days)

### Pattern of FERTILITY for Achievement of Pregnancy

At some time after menstruation a fertile woman notices at the vulva a discharge of mucus which is produced by the cervix. She becomes aware of the sensation this mucus produces at the vulva as she goes about her normal daily activities. This discharge is not an abnormality. It is an indication of good health and tells the woman that now is the time when an act of intercourse may result in pregnancy. The mucus is essential for the healthy function of sperm.

Each woman is an individual and will describe her own mucus pattern. The fertile pattern is a changing developing pattern ending in a slippery sensation and followed by a definite change to no longer slippery. The vulva has a heightened sensitivity near the PEAK. The last day of this slippery sensation at the vulva is known as PEAK and is recognised the day after due to the abrupt change of no longer slippery. This is the time of maximum fertility.

Ovulation occurs usually on PEAK DAY but in some cycles, ovulation may be

Celebrating with women for over 10 years this

# Menopause Day


- Immediate relief from vaginal dryness
- Each application lasts 3 days
- Contains 78.82% w/w purified water
- Non-hormonal
- Available in 3, 6 and 12 pack.
- Easy to use pre-filled applicators

UnitedDrug Consumer | Intrapharma

**Order through your Intrapharma Rep**

KORA HEALTHCARE

delayed until day 1 or day 2 past PEAK. There is only one day of ovulation in a cycle and the ovum lives less than 24 hours.

To Achieve a pregnancy wait for the slippery sensation which occurs at PEAK close to the time of ovulation. Have intercourse then and over next couple of days for best chance to conceive.

As the lifespan of sperm is brief the mucus is essential to support, nourish and help the sperm travel through the womb and fertilise the ovum.

### Pattern of INFERTILITY for Postponement of Pregnancy

Recognising the infertile parttern of the cycle which is unchanging ,is key to using the Billings Ovulation Method to postpone pregnancies. The Basis Infertile Pattern (BIP) is an unchanging pattern. It is identified at the vulva: nothing felt or seen – DRY. Some women experience a slight discharge, but the key here is that it remains the same day after day with a sensation of DRYNESS. A woman is infertile from day 4 past PEAK because she has ovulated, and the egg has regressed and died because it has not been fertilised.

### RULES of Method

Early Day Rules –

- Avoid intercourse on days of heavy bleeding during menstruation
- Alternate evenings available for intercourse when Basic Infertile Pattern has been established
- Avoid intercourse on any day of discharge or bleeding which interrupts BIP.

These Rules apply until PEAK recognised

**PEAK RULE -** From beginning of 4th day following PEAK until end of the cycle, intercourse is available every day at any time. PEAK must be identified before the PEAK Rule is applied.

An experienced teacher will help a woman to recognise these patterns and with the four simple rules, use the Billings Ovulation Method to appreciate the wonderful gift of her fertility.

### HOW TO CHART

On Chart write the date of commencing the record. Each evening briefly describe the observations made during the day, then use the appropriate stamp or symbol to record. Continue charting until next menstruation which is start of next cycle.

When learning the Method and if you wish to avoid pregnancy all genital contact should be avoided for first two weeks until follow-up visit.

### HOW TO LEARN METHOD

It is always advisable to avail of the assistance of an experienced Accredited Teacher.

You can always learn by phone and reading, e-mail, ZOOM or with use of our APPS – Fertility PinPoint or The Billings App. Follow up support is always available and encouraged.

NAOMI-Billings Ireland is a Health Education Charity licensed by the World Health Organisation of the Billings Ovulation Method – WOOMB International, based at the Ovulation Method Research and Reference Centre (OMR&RCA) in Melbourne, Australia.

We re-Affiliate every three years and are Licensed to teach clients and to train teachers who have to Re-Accredit every three years.

**Supported by HSE**

**An Bord Altranais approval sought for Training Courses**

Office at 2 Grove Road, Finglas East (Off Glasnevin Avenue) Dublin 11

Telephone 01 8786156

e-mail: inforequest@naomi.ie

Office Hours 9.30 – 1p.m. weekdays (other times can be arranged)

Registered Company with Guarantee Number: 427048

Charity Number: CHY 6595

We offer the Authentic Billings Ovulation Method with pride. The scientifically and clinically evaluated guidelines cover every stage of reproductive life allowing couples to plan their families naturally. It gives women insight into their own reproductive health allowing them to recognise any need to seek early and appropriate medical help.

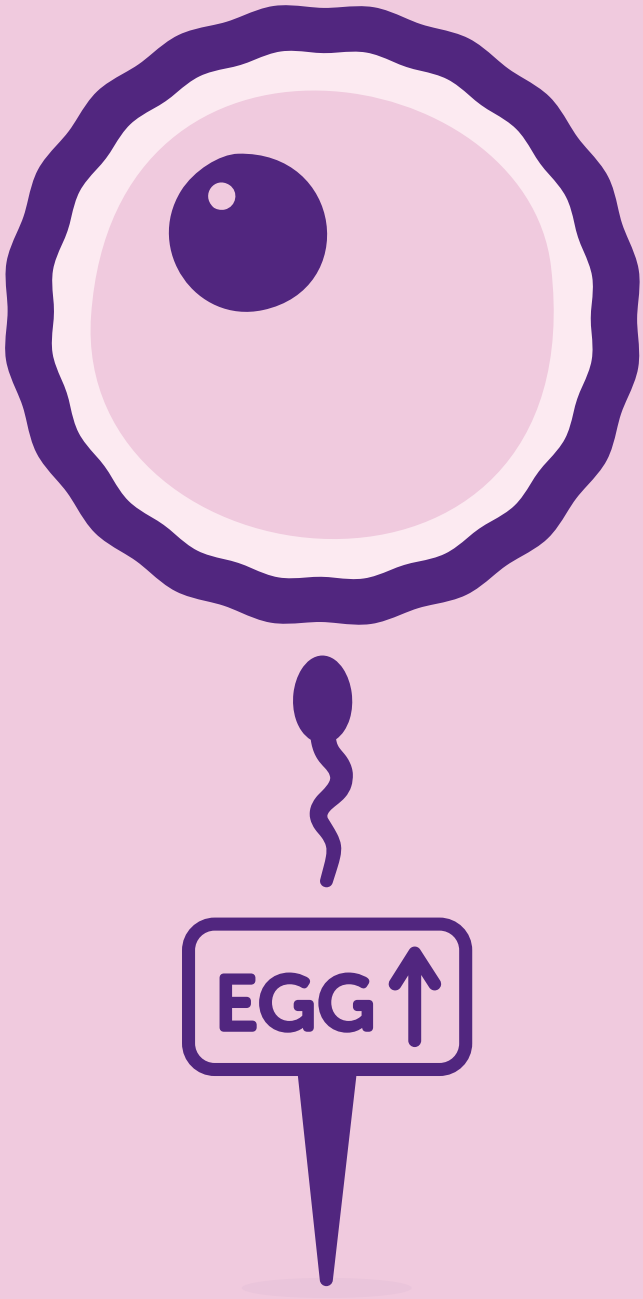
The Billings Ovulation Method is simple to learn, easy to use, scientifically sound, reliable, environmentally friendly and acceptable to all cultures.

# Proceive® Tailored for Fertility and Pregnancy

Proceive Conception is a specially formulated range of fertility and preconception nutritional supplements for men and women. Proceive has been developed by fertility experts using ingredients with clinical science supporting its impact on fertility parameters. Proceive provides the most comprehensive ingredients including Vitamins, Minerals, Amino Acids, CO-Q10 & Omega 3 DHA. This combination of nutrients offer added nutritional support, at a time when the body is reliant on many vital nutrients. Proceive also contains the recommend 400ug of folic acid in the L-Methylfolate format for increased absorption.

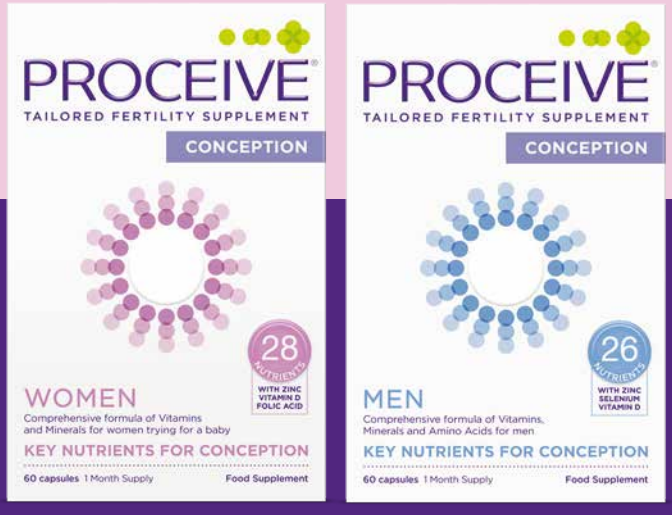
The team behind the brand recently launched their Proceive Pregnancy range, which is a range of tailored nutritional supplements for women who want to ensure they are giving themselves and their baby the best nutritional support throughout pregnancy. The range has been developed by an experienced team of medical and nutritional experts and is uniquely formulated to support the nutritional needs of both mum and baby during each trimester.

“The reason we have taken a trimester-based approach to our products is that during pregnancy your nutritional requirements increase and what’s more, these requirements actually change as the pregnancy processes and the baby develops,” said a company spokesperson.




# Helping nature take its course

Proceive®, nutritional support for conception




**Distributed by Ocean Healthcare | 01 296 8080**

**Available through all Wholesalers**

# Nasal Congestion in Children

*Written by Dr John Joyce, MRCPI, Paediatric Specialist Registrar, Children's Health Ireland@Crumlin*

*Written by Dr Edina Moylett, FRCPI, Consultant Paediatrician, University Hospital Galway and Senior Lecturer, Paediatrics NUI Galway*

**Rhinosinusitis** refers to symptomatic inflammation of the nasal cavity and paranasal sinuses.

**Rhinosinusitis** is a common condition and accounts for a large proportion of presentations to community pharmacy and primary care. It can be subdivided into acute (< 12 weeks) and chronic (>12 weeks).

**Acute rhinosinusitis** (ARS) in children is characterised by the sudden onset of two or more of the following symptoms:

- Nasal blockage/obstruction/congestion
- Discoloured nasal discharge
- Cough (diurnal and nocturnal)

*Acute viral rhinosinusitis* (common cold) accounts for most cases and has a duration up to 10 days. There may be associated fever in the initial period. *Acute post-viral rhinosinusitis* is characterised by worsening of symptoms after five days, or persistence of symptoms beyond 10 days with resolution in less than 12 weeks. This is mostly an inflammatory response, but in a small proportion of cases (0.5-2%), may represent *acute bacterial rhinosinusitis*. This is defined as three or more of: discoloured nasal discharge (unilateral predominance); fever > 38°C; severe local pain (unilateral predominance); deterioration in symptoms ("double sickening"); elevated CRP/ESR. Rhinosinusitis is defined as **chronic** if symptoms persist beyond 12 weeks[1].

The majority of children presenting with symptoms of ARS will have a viral upper respiratory tract infection. Management, therefore, should focus on symptomatic relief and supportive care. Fever and pain may be treated with paracetamol and/or ibuprofen. There is no evidence to support the use of decongestants, antihistamines, or nasal steroids in children with ARS. Nasal irrigation with saline drops/spray may provide some symptomatic relief in ARS and is a mainstay of treatment in chronic rhinosinusitis. Gentle soft suctioning of nasal mucus with a suction bulb may be used in infants or toddlers to relieve obstruction, particularly before feeds. While a small proportion of ARS will develop secondary bacterial infection, this is usually self-limiting, and the limited data available on the use of antibiotics in children with acute bacterial rhinosinusitis showed no difference over placebo[1,2]. Additionally, while acute bacterial rhinosinusitis can be associated with some rare complications, including orbital and intracranial infection, the routine use of antibiotics has not been shown to prevent these[1,3,4]. Monitoring of clinical condition and symptom progression, therefore, is recommended.

*A child with periorbital cellulitis*

Patients presenting with any of the following should be referred urgently for physician review:

- Periorbital oedema/erythema (cellulitis)
- Displaced globe
- Double/blurred/reduced vision
- Ophthalmoplegia
- Severe unilateral or frontal headache (worse than any previous)
- Frontal swelling
- Signs of sepsis or meningitis
- Reduced level of consciousness
- Persistent vomiting

Additionally, physician review should be recommended for rhinosinusitis patients presenting with associated shortness of breath, wheeze, stridor, dehydration, or history of immunocompromise, and failure to respond to supportive measures.

**Allergic rhinitis** (AR), a common condition affecting up to 30% of children and adults, may result in a similar symptom profile to rhinosinusitis. AR can be initially difficult to distinguish from acute viral or post-viral rhinosinusitis, until a pattern emerges.

AR is a chronic condition which occurs most commonly in school-age children and young adults. AR is characterised by watery nasal discharge and/or nasal obstruction, nasal itch, and sneezing, it may also feature itchy, watery eyes (allergic conjunctivitis). Children with longstanding AR may have some of the following clinical findings: nasal speech, allergic shiners (discolouration under the eyes), and a transverse crease on the back of the nose from persistent rubbing of the nose in an upwards direction, also known as the allergic salute.

Symptoms may be seasonal, beginning in spring (triggered by tree pollen), or in summer (grass pollen – peaks in June). Persistent symptoms are mostly triggered by house-dust mite allergy. Persistent/perennial symptoms are more common than purely intermittent or seasonal symptoms, although many patients have perennial symptoms with seasonal exacerbations. Management of AR involves allergen avoidance/reduction where possible.

For house dust mite, this should include washing bed linen at 60°C and damp-wiping surfaces each week. More information and useful factsheets can be found at AllergyUK.org. Dependent on symptom pattern, daily use of an over the counter second generation antihistamine (e.g., cetirizine, loratadine, fexofenadine) should be trialled in the first instance. However, there should be a low threshold to consider the need to refer for intranasal steroid spray +/- sodium cromoglycate eye drops, depending on symptoms severity and response[5]. Specialist allergy referral for immunotherapy for specific allergic triggers is available where indicated and where standard medical therapy has failed.

**References available upon request**

# PARALIEF®

## The complete range of pain relief


**Paralief Range Pain Relief - Full prescribing information is available on request. For retail sale through pharmacies only.**

THE STATED DOSE SHOULD NOT BE EXCEEDED. Please refer to the individual product Summary of Product Characteristics.

PA Holder: Clonmel Healthcare Ltd., Clonmel, County Tipperary:
Paralief 500mg Tablets - Contains paracetamol PA 126/20/1 (24 pack size)
Paralief Hot Lemon 600mg Powder for Oral Solution in Sachet - Contains paracetamol PA 126/20/6
Paralief 500mg Effervescent Tablets - Contains paracetamol PA 126/20/4

PA Holder: Chanelle Medical, Loughrea, County Galway:
Paralief Sinus Tablets - contains paracetamol and pseudoephedrine hydrochloride PA 688/34/1
Paralief Night Film-coated Tablets - Contains paracetamol and diphenhydramine HCl PA 688/38/1
Paralief Extra Film-coated Tablets - Contains paracetamol and caffeine PA 688/50/1

For more information go to **www.clonmelhealthcare.ie**. Date prepared: September 2020

2020/ADV/PAR/079H

CLONMEL HEALTHCARE
STADA GROUP

# Chronic Pain: *A Neuroimmune Phenomenon*

*Written by Professor Connail McCrory MB BCH BAO LRCP&SI FCAI FIPP FPMCAI MD*

*Clinical Professor, School of Medicine, Trinity College Dublin*

*Honorary Consultant, St. James Hospital, Dublin*

***Chronic adult pain is a common problem affecting about 19% of the European population with 61% of these people being unable to work normally resulting in absenteeism, decrease productivity and early retirement with associated negative social and economic impacts and increased demands on healthcare provision. Whilst acute pain is adaptive and protective and usually attributable to a precipitating event chronic pain is not and there is as yet no physiological benefits attributable to chronic pain. Acute pain is generally responsive to anti-inflammatory medication supplemented if necessary with a short course of opioid medication.***

This is not however the case with chronic pain. Chronic neuropathic pain (CNP) in particular is notoriously difficult to treat and is the main reason for attendance at pain clinics.

The factors which affect the transition from acute adaptive pain to chronic maladaptive pain are poorly understood and are an area of investigation because of the high prevalence of chronic pain in society.

It has been noted that patient suffering from chronic pain express symptoms and demonstrate signs of sickness behavior. Sickness or pain related behavior relates to the interaction between the patient and environment, similar to what is seen in patients who have an acute infection on board.

This observation has led to the realization that pain chronicity is probably a central immune-mediated phenomenon. Ongoing research has further identified the relationship between pain and the immune system and pain is one of the four cardinal signs of inflammation.

Depression, anxiety, sleep disturbance and hyperalgesia are commonly problematic in patients with chronic pain.

It is now believed that the neuronal interface which results in these responses includes T cells, macrophages, glial cells and secreted neuropeptides. The nervous system and immune system share a common language mediated at least in part by neuropeptides, (cytokines, chemokines and neurotrophins). Bidirectional communication becomes maladaptive leading to enhanced pain signaling and chronicity.

Whilst there has always been a debate about whether pain chronicity is driven by peripheral stimulation or is solely a central effect it is now quite clear that activation of the dorsal root ganglion and dorsal horn of the spinal cord are central to the development of pain chronicity. Chronic pain occurs when automatic spontaneous non-stimulated sensory unpleasant phenomenon are experience by the patient.[1]

Neuropathic pain may be caused by lesion of the somatosensory system and is estimated to be a chronic problem in 7-8% of the general population in Europe. Access to the central nervous system in humans for the purposes of research is ethically challenging and traditionally difficult to perform. There has been much development in the field of neuroimaging however this has its limitations in terms of regular clinical application.

Chronic neuropathic pain (CNP) remains the greatest clinical challenge. Diagnosis is still heavily dependent on clinical assessment. A multitude of questionnaires are available to help clinicians diagnose CNP but many of these are quite labour-intensive to apply.

The DN4 and LANNS Questionnaires are probably the simplest and easiest to use. Laboratory testing such as nerve conduction studies and sensory evoked potentials, laser evoked potentials, punch biopsy, which can quantify Aδ and C fibres, measuring density

of intraepidermal nerve fibres and quantitative sensory testing are time-consuming and expensive.

The search for an easy to measure inexpensive biomarker continues. The management of CNP relates to both interventional / surgical therapies such as pulsing the dorsal root ganglion and spinal cord stimulation which require hospital attendance including a visit to the operating theatre with anaesthesia and are expensive to carry out.

With the high number of patients suffering from CNP it is simply not practical or within the healthcare budget to provide these expensive therapies to all patients.

Doctors are left with medication as the easiest to obtain therapeutic option however effectiveness is limited by relatively poor efficacy and deleterious side-effects. Number needed to treat (NNT) versus number needed to harm (NNH) ratios are humbling. Two of the most commonly used drug classes are the tricyclic antidepressants and opioids.[2]

As these drugs do seem to have benefit in patients with CNP their mode of action centrally must explain at least in part the pathophysiology of CNP.

Chronic post-surgical pain (CPSP) is disabling and can result in significant physical and economic morbidity for the patient. CNP is the commonest cause of CPSP and may affect up to 40% of patients having surgery depending upon the site and type of surgery.

Thoracic surgery in particular is associated with CPSP. Poor acute pain control in the immediate postoperative setting has been associated with the development of chronic pain but the aetiology is more complex than this.

We investigated the effect of thoracic surgery on human cerebrospinal fluid (CSF) neuropeptides and found that despite adequate acute pain control significant central CSF pro-inflammatory neuropeptide biosynthesis occurred in vivo in patients having a thoracotomy.[3] This was associated with the development of CPSP.

Amitriptyline is probably seen as the most effective drug in the management of neuropathic pain. We examined the effect of amitriptyline on T-cell phenotype and function on human peripheral blood mononuclear cells. This was achieved by Annexin V / propidium staining, flow cytometry and Elisa examination. Levels of secreted cytokines, chemokines and neurotrophins were measured. The results showed that there was no increase in T-cell death however the type of T-cell present was altered by amitriptyline.

The frequency of naïve T cells was significantly lowered after amitriptyline and nortriptyline therapy. The effect of interferon-gamma on CD AT cells was also reduced. Interestingly natural killer T cells are significantly higher following treatment with nortriptyline. Amitriptyline lowered the levels of interleukin 16 and tumour necrosis factor.[4] Amitriptyline is a modulator of both phenotype and function of T cells. Further examination of cerebrospinal fluid (CSF) in patients who responded well to amitriptyline demonstrated a reduction in pro inflammatory pathways of neuronal glial communication and evidence of a neurotrophic effects.[5]

Opioid medication has been used extensively to treat acute, chronic and cancer pain. It is effective in the management of acute and cancer pain however opioid medication in the management of chronic pain is a very contentious issue. This is well delineated in the CDC report 2016. Opioid related phenomena include sedation, tolerance, euphoria, reward, addiction, analgesia, depression, hyperalgesia and death.

There is growing evidence that central signaling maybe responsible at least in part for these phenomenon. Crosstalk between glia, immune cells and neurons, which we refer to as the neurommune interface, occurs by messengers which include cytokines, chemokines, neurotrophins and neuropeptides. Changes in the dynamic of these messengers may be caused by opioid therapy.

There remains debate about whether opioids are truly immunosuppressive. In vivo human opioid mural uniform ecology has remained largely unexplored. The effect of opioid therapy on expression of proteomic and neuropeptide constituents of (CSF) will provide greater insight into the pure mechanisms of action in vivo.

We examined human CSF in patients with CNP medication with opioid (predominantly oxycodone) versus patients with CNP not medicated with opioids using mass spectrometry. 432 proteins were found to be increased in baseline CSF in the patients receiving opioids versus those not receiving opioids. The 10 most differentially increased proteins included somatostatin. In addition 47 neuropeptides demonstrated decreased expression in the group receiving opioids versus the group which were not medicated with opioids.[6]

The quoted studies are referenced at the end of this article for those who wish to explore this topic further. Amitriptyline and opioids are commonly employed therapies which have significant neuroimmune effects.

The amitriptyline work demonstrates the effect is not just related to neuropeptide metabolism but also has a direct effect on T-cell expression and the receptors on the surface of T cells and the neuropeptide secreted from these cells. The opioid study demonstrates that opioid prescription has a major effect on central neuropeptide and protein biosynthesis in humans. The fact that both these drugs have an effect on immune function supports the concept that CNP is a neuroimmune phenomenon.

Again constant surveillance must be provided by both the prescribing doctor and dispensing pharmacist when these therapies are employed because affects on human central peptide and protein biosynthesis in vivo are quite extensive.

**References available upon request**

# How to Increase your Online Pharmacy Sales

Inbound marketing is not something that pharmacists typically concern themselves with. Most independent pharmacy owners don't place a huge emphasis on proactively marketing their products and services. There is rarely a structured, consistent, proactive marketing strategy to build brand awareness, increase footfall and entice new customers. We can kind of get away with it due to the nature of retail and the importance of location. People will see a new store in their town and curiosity will get the better of them. They will pop in, see your ranges, meet your staff and hopefully spread the word about your store.

Written by Colm Baker,
The Social Pharmacist

Unfortunately, when you launch your pharmacy website, it's not as easy. Launching a pharmacy website is like opening a retail pharmacy in the desert. You have no passing trade. You're not going to make any money unless you proactively bring people to your store. When you launch your pharmacy website, you need to proactively market your online store to increase awareness, entice people to visit your website and convince them to purchase your products.

Once upon a time, you could just launch a website and easily rank on page one of Google or get huge exposure on social media. Nowadays, it's not as easy. There's too many competitors, you need to spend money on paid adverts to get huge exposure on social media and you're competing with pharmacy chains who have been doing this for years, with specialist marketing teams that are spending tens of thousands on advertising every month.

I hate to dash your dreams of sipping cocktails on a beach in Bali counting your millions a few months after you launch your pharmacy website but it's not that simple to grow a profitable online pharmacy business. It definitely is possible but it takes a lot of work and you need to implement a comprehensive digital marketing strategy.

To create a sustainable, profitable online pharmacy business you need to implement the tactics listed below with a coherent digital marketing strategy that engages your customers at all four phases of your potential customers' journey.

**Phase 1:** You need people to know that you have an online store.

**Phase 2:** You have to actually compel them to go and visit your website.

**Phase 3:** You need to persuade them to purchase.

**Phase 4:** You need to maximize their lifetime customer value.

You should create a digital marketing ecosystem where you are using many of these tactics simultaneously to move as many people as possible through these four phases as quickly as possible, with the greatest value.

**Organic Social Media Marketing:** refers to the regular posts that you publish on social media. It's a long-term strategy that should be used on a daily basis to position your brand as healthcare experts and to build a connection with your followers so they get to know, like & trust you.

Unfortunately, most independent pharmacies use social media to spam their followers with deals & discounts rather than using it to build their brand positioning or enhance the connection with their followers. Don't forget that social media marketing is a disruptive form of marketing. People are browsing social media to find out the latest news, have a laugh and keep up to date with their friends, favourite celebrities, and sports teams. They're not looking for your "amazing" discounts on shower gels.

While you may think the only way to sell is to showcase offers, by taking this approach you will reduce your engagement rates while also creating the perception of being a discount retailer. What you should be doing is using social media to educate & infotain: answer questions, provide advice, show your personality, take them behind the scenes of working in a pharmacy. If you're a bit camera shy then focus on creating posts that provide healthcare advice, tips to manage conditions, reduce symptoms & product recommendations.

**Social Media Paid Advertising:** Most people have used the blue "Boost" button on Facebook to push out their posts to more people. However, there are much more sophisticated & efficient advertising tools available when you are selling online. Facebook's Ads Manager is undoubtedly the best & most relevant social media advertising platform for independent pharmacies. It allows you to advertise on Facebook, Instagram, Messenger and other sites & apps that have partnered with Facebook. You can start with advertising budgets as low as €1/day but you'll need to spend a lot more than that to scale your online sales significantly.

The huge amounts of data that Facebook has collected on all of its users has allowed them to create a very effective advertising platform. You can target specific people based on their interests, behaviours and demographics. You can also advertise specifically to people who have previously engaged with your pharmacy brand online. This process is known as remarketing and is one of the most powerful tactics to grow your online sales. You can create a wide range of adverts including single images, videos, stories, carousels with multiple videos and/or images and immersive mobile landing pages. These adverts can be linked directly to the products on your website to enhance conversion rates. When you publish your adverts, Facebook will use its data systems to optimize their delivery to increase your sales.

**Search Engine Optimization (SEO):** involves using a range of tactics to improve the quality and quantity of website visits that you receive from search engines. With SEO, you are attempting to rank higher in search engines for relevant keywords that your target market is using. For example, you might make changes to existing website pages, images, or publish

new content to be deemed more relevant for terms like “online pharmacy ireland”. SEO is a long-term strategy that does not involve spending money on advertising. However, it does take time, skill and experience to improve your rankings and outrank your competitors for relevant keywords. A major benefit of SEO as opposed to paid advertising is that the website traffic and sales won’t dry up when you stop investing in it. But if your competitors are actively developing their SEO they could climb above you in the rankings.

**Google AdWords:** is the search engine version of using paid advertising on social media to get greater exposure. When you search for anything on Google, you’ll typically see that the first and last few results on the page are sponsored ads. With Google AdWords, you are paying Google to attempt to be ranked higher than competitors for a particular search term. Doing this profitably takes a lot of time, skill and testing but also requires a good website conversion rate.

Google AdWords is typically much more competitive and thereby expensive than social media advertising. But you are advertising to people with greater buyer’s intent i.e. who are actually searching for products or services rather than disrupting their browsing on social media. There is far less advertising space and much more competition for high value search terms. You need to make sure that your product pages, checkouts and website in general, is optimized to convert as many visitors as possible into customers.

**Email Marketing:** You’re probably familiar with the most basic form of email marketing: the monthly newsletter. Email marketing tends to get a bad reputation by marketers trying to sell new tools & tactics but it remains one of the most profitable forms of online marketing. Once you have collected your email subscribers in a GDPR-compliant manner, you should use email marketing regularly to engage your subscribers, offer value, build brand awareness and increase sales.

When you start using paid advertising on social media or Google, you will always be worrying about how much you’re spending. When it comes to organic social media you will be frustrated that you only reach a small percentage of your followers. Email marketing offers a free (aside from minor software fees) to immediately contact all of your subscribers at specific times. This can be of particular benefit during key seasonal times such as Black Friday, Valentines Day etc.

The other less known side of email marketing is what are called automations. When you integrate your email marketing software with your website you can trigger pre-created emails to be sent automatically based on people's actions on your website. A simple version of this is the confirmation email customers receive after they complete an order. There are more comprehensive follow up automations that you can use to grow your website traffic and increase your sales without doing any additional work.

**Affiliate Marketing:** is a type of referral scheme where you provide a unique trackable link for your website to people who will market your website for you. Any sales that come from people clicking on this affiliate link will be tracked and they will receive a commission in return. Affiliate marketing can start out as simple as a referral scheme with your customers or it can involve experienced marketers who should be able to grow your sales further. The benefit of affiliate marketing is that you don’t have to make payments up front and you will only have to pay when a sale is made. Therefore, you can build a lot of brand awareness & generate leads for free. The downside is that it’s hard to find reliable affiliates and you also need to provide them with content guidelines & support to ensure they maintain the integrity of your brand.

**Influencer Marketing:** Another type of referral marketing where you’re paying someone who has created a following online to get exposure for your brand. Influencer marketing often gets a bad reputation and rightfully so in many cases. You could pay a pretty penny up front and be left with very little in return. An affiliate arrangement is more secure and also provides greater potential upside for them too.

You need to be very diligent when choosing what influencers you’re going to work with. Have they an engaged following who will be interested in your products? Are they constantly spamming their following with offers? Can they show you past results of campaigns? Is their audience relevant to your business? What style of content will they create? Will they fit with your brand? A good way to get started is to work with some local or niche “micro-influencers” who have built a small but engaged following. Test out the process before spending large sums working with more high profile influencers.

Ideally, you want your team & pharmacy featured in the content whether it’s showing them around your pharmacy, doing a Q&A, showcasing the latest products or taking them on a tour of your website. The more connection you build with their audience, the more likely they will be to become customers.

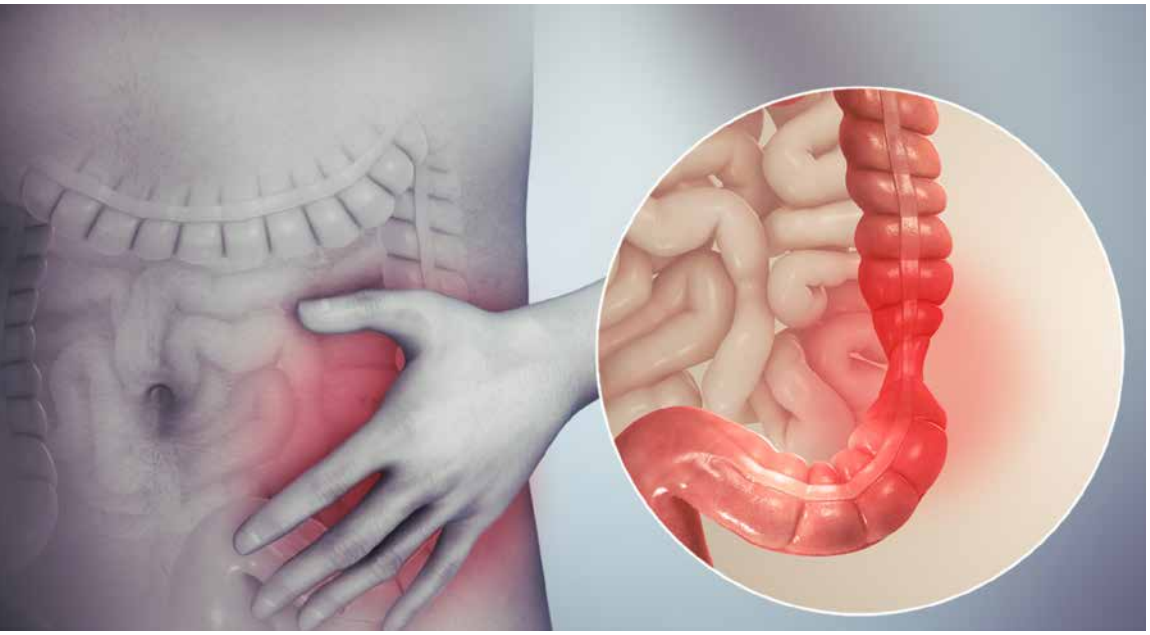
**Content Marketing:** includes your social media content but in particular, I want to use this section to focus on long-form content such as blogs, webinars, and guides you can create to advise your audience and answer their questions. Long-form content is a great way to position your brand as healthcare experts but also can be used to boost your SEO, create engaging social media content and generate leads. This type of content is a great way to build trust & connection with your audience.

**Traditional Marketing:** using channels such as newspapers, radio stations, PR, TV, billboards, leaflet drops etc. are by no means near the top of the list when it comes to increasing your online sales but they can definitely form a part of your marketing strategy.

As you can see there are lots of different ways to increase your online sales. You need to define which tactics are the best for your pharmacy given your current experience, resources and advertising budget. Then you need to implement these tactics with a coherent marketing strategy that will build brand awareness, attract more visitors to your website, convert more of these visitors into customers and enhance the lifetime value of these customers. You can learn more with our free webinar on **www.thesocialpharmacist.com/webinars** which expands further on these tactics.

# IBS: What Pharmacists need to Know

Irritable bowel syndrome (IBS) is quite common with as many as 1 in 5 people affected. It is twice as common in women as men and happens most often to people in their 20s and 30s.



IBS is a disorder of the gut whereby the function of the gut is disturbed. However there are no physical or structural abnormalities. It causes a variety of symptoms, which are discussed in further detail below. It usually first appears in teenagers and young adults.

Symptoms of IBS include loose, frequent stools, constipation, bloating, and abdominal pain and cramps. Patients may notice symptoms following the intake of specific foods or that symptoms, such as stool consistency or pain location, change over time. Patients may also present with headache, lethargy, nausea, bladder symptoms or faecal incontinence.

According to Theresa Lowry Lehnen, Clinical Nurse Specialist, RNP and Associate Lecturer at IT Carlow and PRO of the Irish General Practice Nurses Association, the causes and pathophysiology of IBS is complex and remains poorly understood. Irish Pharmacy News spoke to her about the reasons for this and current management and treatment options available to community pharmacists.

"Theories include combinations of gut-brain axis problems, gut motility disorders, pain sensitivity, infections including small intestinal bacterial overgrowth, neurotransmitters, genetic factors, and food sensitivity," she explains.

"Onset may be triggered by an intestinal infection or stressful life event. It is thought that a number of factors may contribute to development of the disorder. Genetic predisposition and environmental interactions, such as familial susceptibility and psychosocial stressors, have been implicated in the multifactorial pathogenesis of IBS.

"Diet and stress have been proposed as contributing factors to this heterogeneous disorder. Because stress has been identified as a mechanism in the development of IBS, the major components of the stress response system, the autonomic nervous system (ANS) and the hypothalamic-pituitary-adrenal (HPA) axis, have been the subject of numerous investigations of IBS.

"IBS is commonly associated with other functional, somatoform and mental disorders. In over 20% of cases, there is an overlap of IBS with functional GI disorders of the upper GI system particularly functional dyspepsia and gastroesophageal reflux disease and of the lower GI system such as diarrhoea, incontinence, pelvic floor dyssynergia and constipation. Psychiatric comorbidities are present in approximately 50% of IBS patients and include depressive symptoms, anxiety and eating disorders."

**Classification Criteria and Diagnosis**

IBS has been categorised as a functional bowel disorder i.e., it is not associated with any structural or biochemical abnormalities in the GI tract. No specific laboratory or imaging tests can diagnose irritable bowel syndrome. The Rome criteria is used to diagnose IBS when the presence of organic disease such as IBD, colon cancer, and coeliac disease have been excluded.[1, 2]

Theresa continues, "The Rome III classification diagnostic criteria, served as the symptom-based, diagnostic criteria for IBS since its release in 2006 and subtypes IBS patients based on predominant stool pattern: constipation (IBS-C), diarrhoea (IBS-D), mixed (IBS-M) or unsubtyped (IBS-U). Rome III classified the disorder by symptom onset greater than six months and recurrence at least three days per month during the last three months. Diagnostic criteria required abdominal discomfort or pain to be associated with two or more of the following: improvement with defecation, onset associated with change in the form of stool, or onset associated with a change in the frequency of stool.

"In early 2016 the Rome Foundation released **Rome IV**, an **updated classification system** for conceptualizing and diagnosing functional gastrointestinal disorders.[1] The Rome IV definition of IBS maintains symptom chronicity greater than six months and current activity present within the prior three months, however, symptom frequency has been changed to at least one day per week from at least three days per month. Pain related to bowel movements is required, rather than just improving with bowel movements, because, in some cases, pain can worsen after bowel movements. The "onset" of abdominal pain has been eliminated from the association of pain with changes in stool.

"The term "Discomfort" was eliminated from the criteria because it is non-specific and has different meanings in different languages."

**How to Diagnose?**

In turning to the diagnosis of IBS, Theresa says, "To make an accurate diagnosis of IBS, it is generally recommended to incorporate Rome IV Criteria along with the patient history including dietary questions, physical examination including abdominal and anorectal examination, laboratory tests such as full blood count, C-reactive protein or erythrocyte sedimentation rate (ESR), possible coeliac disease serology, and when indicated a colonoscopy and/or upper gastrointestinal endoscopy and other tests.

"An abdominal X-ray can be considered to rule out faecal loading if constipation is the predominant symptom. When Rome IV criteria are present and alarm features are absent, only a limited number of laboratory tests are recommended without the need to perform invasive investigations.[10]

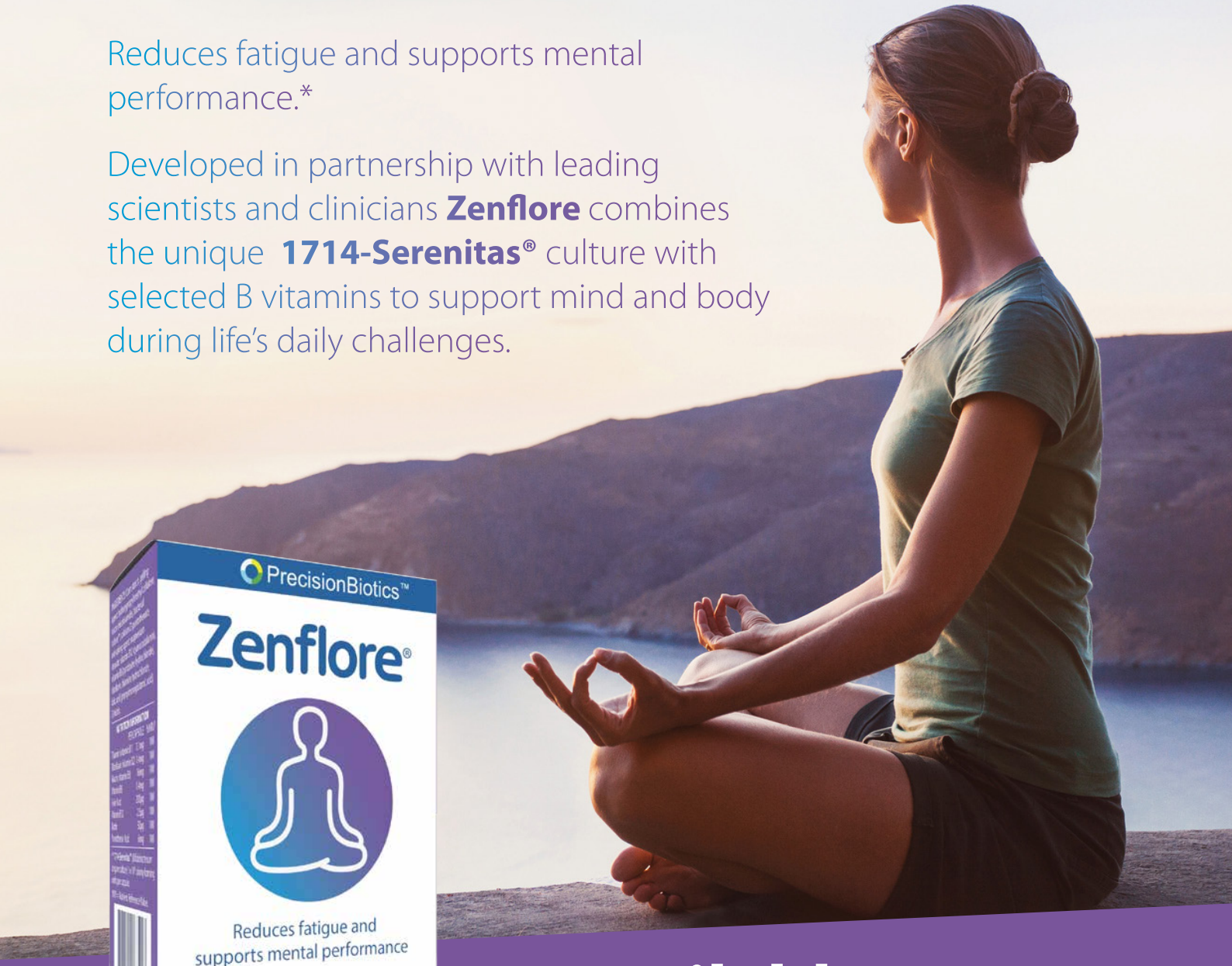
"Patients may have IBS-type symptoms for many years without presenting to medical care, often self-managing their symptoms without medical input, and some may never consult. Nevertheless, lower gastrointestinal symptoms frequently prompt people to present to primary care, accounting for approximately 1 in 12 of all consultations.[11]

"It is important to question patients about dietary and medication changes, life stressors and support networks, as part of the diagnostic assessment. Alternative

# Zenflore®

Reduces fatigue and supports mental performance.*

Developed in partnership with leading scientists and clinicians **Zenflore** combines the unique **1714-Serenitas®** culture with selected B vitamins to support mind and body during life's daily challenges.




## Available now

- ✓ **Clinically studied and shown to reach the digestive system with its properties intact.**
- ✓ **No refrigeration required**
- ✓ **Vegetarian**
- ✓ **Once a day easy to swallow capsule**
- ✓ **Soya and gluten free**
- ✓ **Lactose free**

PrecisionBiotics™

Distributed by Pamex Ltd

Email: info@pamex.ie | Phone: 094 9024000

PameX Limited

***Pantothenic Acid:** Contributes to normal mental performance; **Biotin, Folate, Niacin, Thiamine, Vitamin B12, Vitamin B6:** Contribute to normal psychological function; **Folate, Niacin, Pantothenic Acid, Riboavin, Vitamin B12, Vitamin B6:** Contribute to the reduction of tiredness and fatigue; **Biotin, Niacin, Pantothenic Acid, Riboavin, Thiamine, Vitamin B12, Vitamin B6:** Contribute to normal energy yielding metabolism. | Zenflore, PrecisionBiotic, 1714 and 1714-Serenitas are trademarks of Alimentary Health Ltd. Copyright 2019.

Theresa Lowry Lehnen, Clinical Nurse Specialist, RNP and Associate Lecturer at IT Carlow and PRO of the Irish General Practice Nurses Educational Association

diagnoses that should be considered when patients present with IBS symptomatology include coeliac disease, microscopic colitis (MC), inflammatory bowel disease including Crohn's disease and ulcerative colitis, bile acid malabsorption, colorectal cancer, and dyssynergic defecation.[3] Once a diagnosis of IBS has been made, the general practitioner should endeavour to follow-up with the patient within the next 2 months to ensure symptoms are not getting progressively worse, which may be indicative of a more sinister underlying disease process.[11]

The British Society of Gastroenterology new guidelines on the management of irritable bowel syndrome (2021) are available at: https://gut.bmj.com/content/70/7/1214. The aim of the guideline, commissioned by the BSG, is to review and summarise the current evidence to inform and guide clinical practice, by providing a practical framework for evidence-based management of patients.[11]

**Treatment**

Theresa says that while there is no known cure for IBS, treatment is focused on symptom control, in order to improve quality of life, with a combination of lifestyle and dietary advice and the use of pharmacological therapies often required.

She adds, "Pharmacological management including laxatives, antidiarrhoeals and certain antispasmodics is centred on treatments that alleviate symptoms of IBS, but which are not specifically authorised for IBS itself.

"Education and reassurance is an important aspect of patient care and treatment, explaining the natural history of the disease and providing reassurance that it is a benign condition. It is important to build up a good rapport with the patient, including them in the decision making process and ensuring their voice and concerns are heard as well as validating their symptoms.

"Management of IBS involves an integrated approach and treatment options include establishment of an effective patient-provider relationship, education, reassurance, nutritional interventions, pharmacological and psychological therapy.[2, 5.9, 10] The clinician patient relationship, continuity of care, empathy, including acknowledgement of the impact of symptoms on daily life, a shared understanding of IBS and shared decision-making can assist in providing appropriate education, signposting to reputable online information or peer support, reassurance, advice and management options.

"There should be a realistic discussion concerning the limitations of all available treatments for IBS to manage expectations. It is important to stress that cure is unlikely, but substantial improvement in symptoms, social functioning and quality of life is achievable.[11]

**Pharmacological Therapy**

The choice of pharmacological therapy depends on the nature and severity of IBS symptoms, shares Theresa.

"Many drug treatments options for IBS are available over the counter. **Antispasmodics** are among the most frequently used over-the-counter treatments for IBS, and can be broadly divided into antimuscarinics and smooth muscle relaxants. Antimuscarinics, including dicycloverine, propantheline, otilonium bromide and hyoscine butylbromide reduce intestinal motility, whereas alverine and mebeverine are direct-acting intestinal smooth muscle relaxants.[11] Butylscopolamine, due to its ability to antagonize the binding of acetylcholine to the muscarinic receptor at the neuromuscular junction, leads to smooth muscle relaxation, however, due to anti-muscarinic adverse effects such as constipation, it should not be used in patients with IBS-C.[10]

"Mebeverine, a spasmolytic without atropine-like side effects, has high efficacy for abdominal pain and reduction in daily defecation frequency, as well as an improvement in well-being, with good tolerability with minor complications. Peppermint oil inhibits smooth muscle contraction through calcium channel blockade and has been proven to reduce IBS symptoms, being a safe and effective treatment for IBS. Antispasmodics are thought to improve symptoms of abdominal pain and have been shown to provide short-term relief of symptoms.[5, 10]

"Osmotic **laxatives** such as polyethylene glycol are often recommended to improve constipation for those with IBS-C, however, they have not been shown to improve abdominal pain or bloating. Stimulant laxatives may also be used. Lactulose is not recommended, as it increases gas production, causes bloating and can exacerbate symptoms.[2] Patients who have not responded to laxatives from the different classes and who have constipation for at least 12 months can be treated with linaclotine, however, caution must be taken due to its predisposition to fluid and electrolyte imbalance. Linaclotine is contraindicated in GI obstruction-inflammatory disease.[5]

"Loperamide hydrochloride is the first line choice of **anti-motility drug** for relief of diarrhoea due to its action on opioid receptors in the GI tract, and because it does not readily cross the blood brain barrier. It inhibits peristalsis, prolongs gut transit and reduces faecal volume. As constipation is an adverse effect, it should be used with caution for patients with IBS-M. Patients with IBS should be advised how to adjust their dose of laxative or anti-motility drug according to stool consistency with the aim of achieving a soft, well-formed stool.[2, 5]

"A low dose tricyclic **antidepressant** (TCA) such as amitriptyline hydrochloride (unlicensed indication) can be used for abdominal pain or discomfort as a second line option in patients who have not responded to antispasmodics, anti-motility medications or laxatives. They should be commenced at a low dose e.g., 10 mg amitriptyline once a day and titrated slowly to a maximum of 30–50 mg once a day.[11] An SSRI may be considered in those who do not respond to a tricyclic antidepressant. As with tricyclic antidepressants, they can be initiated in primary or secondary care, but careful explanation as to the rationale for their use is required, and patients should be counselled about their side-effect profile.[5, 9, 11] Psychological interventions can be offered to patients who have no relief of IBS symptoms after 12 months of drug treatments. There is good evidence that psychological treatments directed against IBS symptoms, especially cognitive behavioural therapy (CBT), and hypnotherapy, are helpful for many patients' symptoms, but unfortunately these are not always readily accessible.[5, 11]

**"Diet and lifestyle changes** are important for effective self-management of IBS. First-line dietary advice should be offered to all patients with IBS. Patients should be encouraged to increase physical activity, with recommended guidelines of 30 minutes at least five days a week and advised to eat regularly without missing or leaving long gaps between meals. Dietary advice should also include limiting fresh fruit consumption to no more than three portions per day. The fibre intake of patients with IBS should be reviewed."

A growing focus of clinical research has been to improve IBS symptomatology through dietary modifications, she says.

Parallel to the focus on dietary modifications are efforts to alter the intestinal microbiota. Undigested food is used by intestinal microbes (GI microbiota) upon entering the intestine, and microbiota play a major role in gastrointestinal processes and overall health.[8]

**New Therapies**

Efforts in identifying the different pathophysiological mechanisms involved in symptom generation have allowed the development of new symptom-based and target therapies. New insights and ongoing research into trials of novel treatments, including pharmacological, dietary and behavioural therapies, device-based treatments and faecal microbiota transplantation will hopefully bring a better quality of life to patients with IBS, as they contribute to a new understanding of this syndrome.

**References available on request**




ATHENA
PHARMACEUTICALS

# TRIED & TRUSTED




**Further prescribing information or the SmPC is available on request from:** Athena Pharmaceuticals Ltd, 4045 Kingswood Rd, Citywest Business Campus, Dublin 24. medical@athenapharm.com Tel: +353 (1) 4688202. Legal Category: POM MA Holder: Cheplapharm, Arzneimittel GmbH, Ziegelhof17489, Greifswald, Germany. **Adverse events should be reported to:** medical@athenapharm.com or Health Products Regulatory Authority www.hpra.ie e: medsafety@hpra.ie Tel +353 (1) 6764971

# A Burning Issue

## Theresa Lowry Lehnen talks all things GORD

Theresa Lowry Lehnen, Clinical Nurse Specialist, RNP and Associate Lecturer at IT Carlow and PRO of the Irish General Practice Nurses Educational Association gives IPN readers an overview of the key themes in managing and treating Gastro-oesophageal Reflux Disease (GORD).

**What is GORD?**

GORD is caused by acid leaking up from the stomach and coming into contact with the oesophagus. While the stomach is able to withstand litres of acid without pain, the gullet is not. GORD has a significant impact on quality of life and productivity, with sufferers reporting impaired sleep and interference with social activities and work.

Incidence of GORD is certainly rising as obesity rates accelerate. People are also binge drinking and eating more fatty or calorific food, which increases acidity levels and contributes to poorer digestive health.

**Common Symptoms**

GORD is typically a very treatable disease, but many people don't know they have it because its symptoms are associated with numerous other conditions.

Common symptoms of GORD include:

- Chronic heartburn
- Regurgitation
- Chest pain or discomfort
- Chronic cough, sore throat, and/or hoarseness
- Sleep disturbances and night-time symptoms
- Belching, gas, and bloating
- Nausea
- Intolerance of certain foods
- Sour taste in the back of the mouth

It's normal to experience reflux symptoms every now and then, especially after a large meal. Acid reflux is considered GORD if symptoms occur at least twice per week or moderate to severe symptoms occur once a week.

Other symptoms include vomiting, halitosis, anorexia, dysphagia, cough and respiratory or oropharyngeal symptoms. Theresa says, "GORD may be just an occasional symptom for some people, but for others it can be a severe, lifelong condition. Left untreated, GORD can cause considerable discomfort and a poor quality-of-life. Medical attention should be sought and symptoms investigated when GORD is severe, occurs several times a week, over-the-counter medications are not helping, dysphagia or symptoms such as vomiting, haematemesis, anaemia or unexplained weight loss occur, that could suggest a more serious problem.[1, 10]

"Several factors may increase the risk of developing GORD. First degree relatives of patients with GORD are four times more likely to develop symptoms, raising the possibility of a strong genetic contribution to the aetiology.[11]

"Medicines such as calcium-channel blockers, nitrates and non-steroidal anti-inflammatory drugs (NSAIDs) can cause GORD or make the symptoms worse."[10]

**Diagnosing GORD**

She adds, "A presumptive diagnosis of GORD can be made based on the typical symptoms of heartburn and acid regurgitation. Tests for GORD include, endoscopy, barium swallow or meal, manometry, 24 hour pH monitoring and blood tests. A Full Blood Count should be taken to assess for anaemia, which could be a sign of internal bleeding.[8]

"GORD can be classified according to the presence or absence of erosions on endoscopic examination. Absence of erosions are classified as non-erosive (NERD), whereas GORD symptoms with erosions is classified as erosive oesophagitis.[2] The primary role of endoscopy is to look for complications and to exclude other diagnoses.

"Manometry is used to assess how well muscle at the distal end of the oesophagus is functioning. A tube containing pressure sensors can measure the pressures in the oesophagus and help determine whether surgery may be necessary.[8]

"A barium swallow, or barium meal, may be required to assess swallowing ability and look for any blockages or abnormalities in the oesophagus.[8]

"24 hour pH monitoring may be necessary to measure the acidity level in the oesophagus and confirm a diagnosis of GORD. It is the gold standard and most objective test to diagnose the reflux disease and allows monitoring of GORD patients in their response to medical or surgical treatment.[8]

"A urea breath test is the examination of choice for patients under the age of 50 years presenting with dyspepsia. It is recommended as a non-invasive test for active H.pylori infection, but does not confirm or establish a diagnosis of GORD."[2]

**Treatment and Management**

The management of GORD includes pharmacotherapy, dietary and lifestyle changes and in some cases surgery," Theresa explains. "Initial treatment is guided by the severity of symptoms and treatment is adjusted according to response. The extent of healing depends on disease severity, treatments chosen and the duration of therapy.

"Patients should be advised about lifestyle changes, avoidance of excess alcohol and consumption of aggravating foods such as fats. Other measures include smoking cessation and weight reduction if applicable, raising the head of the bed when sleeping, and the avoidance of wearing tight fitting clothing and bending down after a meal.[5, 12]

# Trust the UK's No.1 brand for piles


AnuSol™

# Effective relief from piles, proven to:

- shrink piles
- reduce inflammation
- soothe itching
- relieve discomfort

UnitedDrug Consumer

**For more information please contact your Pemberton Rep or Customer Service on 01-4632424**

Anusol™ Cream (GSL): Each 100g contains Bismuth oxide 2.14g, Balsam Peru 1.8g, Zinc oxide 10.75g. Anusol™ Suppositories (GSL): Each suppository contains: Bismuth subgallate 59mg, Bismuth oxide 24mg, Balsam Peru 49mg, Zinc oxide 296mg. Anusol™ Plus-HC Ointment (P): Each 100g contains: Hydrocortisone acetate 0.25g, Benzyl benzoate 1.25g, Bismuth subgallate 2.25g, Bismuth oxide 0.875g, Balsam Peru 1.875g, Zinc oxide 10.75g. Indication. For the symptomatic treatment of internal and external (ointment only) haemorrhoids and pruritus ani. MA holder. Church & Dwight UK Ltd., Premier House, Shearway Business Park, Pent Road, Folkestone, Kent, CT19 4RJ. Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: Anusol cream:
https://www.medicines.org.uk/emc/product/1486/smpc; Anusol Suppositories: https://www.medicines.org.uk/emc/product/1488/smpc; Anusol Plus-HC Ointment: https://www.medicines.org.uk/emc/product/1470/smpc. Latest revision of SmPCs: April 2018.

"Initial management for mild symptoms, may include the use of **antacids and alginates** which reduce reflux and protect the oesophageal mucosa. **Histamine $H_2$ –receptor antagonists** such as ranitidine may be used to relieve symptoms and permit reduction in antacid consumption.

"For more severe symptoms and patients with oesophagitis, oesophageal ulceration, oesophagopharyngeal reflux and Barrett's oesophagus, treatment involves the use of **Proton pump inhibitors (PPI)**.

"If GORD is unresponsive to diet and lifestyle changes in pregnant women, antacids or alginates can be used. If this is ineffective ranitidine a $H_2$ – receptor antagonists may be used. Omeprazole is reserved for pregnant women with severe or complicated reflux disease."

She continues, "Antacids containing aluminium or magnesium compounds can often relieve symptoms in ulcer dyspepsia and non-erosive GORD. Antacids are best given when symptoms occur or are expected, usually between meals and at bedtime. Conventional doses of liquid magnesium aluminium antacids 3-4 times daily promote ulcer healing but are not as effective as antisecretory medication. Magnesium containing antacids tend to be laxative in nature, while aluminium containing antacids can be constipating. Antacid products containing both magnesium and aluminium can reduce these colonic side effects. Sodium bicarbonate should no longer be prescribed alone for the relief of dyspepsia, but is present as an ingredient in many indigestion remedies.

"Caution must always be maintained with the use of **$H_2$ receptor antagonists** and **proton pump inhibitors** as they can mask the symptoms of gastric cancer. Particular care is required in patients presenting with alarm features.

"In such cases, malignancy should be out ruled before treatment commences. Side effects of $H_2$ receptor antagonists include diarrhoea, headache and dizzyness and the $H_2$ receptor antagonist cimetidine should be avoided in patients stabilised on warfarin, phenytoin and theophylline. Side effects of PPIs include GI disturbances, dizzyness, headache and sleep disturbances. Patients at risk of osteoporosis on PPIs should maintain an adequate intake of calcium and vitamin D and if necessary receive other preventative therapy. Long-term use of PPIs has been linked to complications, such as vitamin and mineral malabsorption, pernicious anaemia, gastrointestinal infections, gastric cancer and dementia."[2, 5]

Theresa concludes, "Gastroesophageal reflux disease is a common disorder, and is one of the most frequent conditions encountered in primary care. Treatment and management of GORD symptoms is important and early intervention has the potential to reduce serious complications.

"The goal of treatment is to effectively control symptoms, prevent complications and improve the patient's quality of life. Special attention should focus on reducing the rate of refractory GORD and complications such as Barrett's oesophagus and adenocarcinoma. Knowledge and understanding of the safe and effective use of medications in the treatment of GORD especially PPIs, prevents inappropriate use, and addresses their adverse reactions and interactions with other medications. The clinical benefits and risk of using PPIs should be evaluated for each individual. Assessment, monitoring, audit and evaluation for disease activity, progression, and effects of the therapeutic regime on a patient with GORD is important and a continuous process. For patients requiring long term PPI therapy the clinical effects should be reviewed regularly and treatment adjusted as required. The lowest dose of a PPI that controls symptoms should be used. Implementing person-centred care, monitoring and evaluating symptoms, outcomes and responses to therapy plays a pivotal role in managing the illness and improving the patient's quality of life."

**GORD in Infants**

In most babies, reflux is nothing to worry about (as long as they are healthy and gaining weight as expected). However, in some cases (though very few) reflux can cause a lot of pain when strong acid travels up into the food pipe. When reflux becomes painful and it happens frequently, this is known as 'gastro-oesophageal reflux disease' (GORD).

Baby reflux symptoms include:

- constant or sudden crying when feeding
- bringing up milk during or after feeds (regularly)
- frequent ear infections
- lots of hiccups or coughing
- refusing, gagging or choking during feeds
- poor weight gain
- frequent waking at night

Theresa adds, "If necessary, suitable alginate preparations can be used instead of thickened feeds. For older children lifestyle changes may be helpful, followed if necessary by an alginate containing preparation. Infants or children who do not respond to these measures or who have complications such as oesophagitis or a respiratory disorder, need to be referred to hospital as a $H_2$ –receptor antagonists may be required to reduce acid secretion."

**References available on request**

# Boots Raise over €2 million

Boots Ireland were delighted to recently announce that they have raised over €2 million for the Irish Cancer Society, enabling more than 6,300 nights of end-of-life Night Nursing care for people with cancer.

"Our team members, patients and customers have come together to raise funds for this essential service to ensure cancer patients receive the end-of-life care needed to allow them to remain in their own home," they said via their Linkdin.

Earlier this year, for the fourth year running, Boots Ireland were the main sponsor of the Irish Cancer Society's Daffodil Day. Daffodil Day is the Irish Cancer Society's biggest fundraiser, taking place each year in March and raising millions of Euro to support cancer patients and their loved ones by providing free advice and support, as well as by funding lifesaving cancer research.

Due to Boots Ireland team members' continued support and the generosity of customers, through the sale of Daffodil pins in stores and virtual fundraising, more than €160,000 was raised, which equates to more than 460 nights of care.

# medithyme COUGH SYRUP

## Can be used to treat a chesty cough

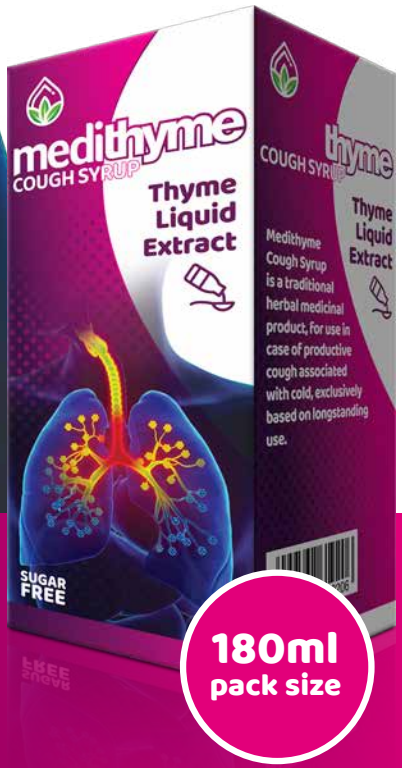
(productive cough)*

Contains thyme liquid extract

Sugar free

Suitable for vegans

Gluten free




180ml pack size

**Traditional herbal medicinal product**

**Children from 12 years and adults: 15ml, 4 times a day**

Medithyme Cough Syrup contains liquid extract from Thymus vulgaris L., herba (Thyme herb). Contains: ethanol, maltitol (E965) and benzoate salt (E211). For oral short-term use only. **Contraindications**: Hypersensitivity to thyme or to other members of the Lamiaceae (mint) family, or to any of the excipients. For supply through general sale. A copy of the summary of product characteristics is available upon request. TR 126/319/001. TR Holder: Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary. Date prepared: July 2021. 2021/ADV/MED/073H. *Medithyme Cough Syrup is a traditional herbal medicinal product, for use in case of productive cough associated with cold, exclusively based on longstanding use.

# Health Literacy Quality Mark for Haven Pharmacy Group

The Haven Pharmacy group is the first group to have all 49 branches receive the Crystal Clear health literacy quality mark.


Pictured is Clare McNally, NALA Communications Manager with Daragh Connolly, Chairman of the Haven Pharmacy Group after receiving the Crystal Clear health literacy quality mark on behalf of all Haven Pharmacy stores nationwide

This mark recognises the critical role pharmacies play in helping people understand their health issues and the steps they need to take to improve their health. The mark is awarded to pharmacies where there is evidence of, and commitment to, providing a literacy friendly service.

A new International Health Literacy Survey, due to be published by the Department of Health in October, shows that 28% of the Irish population have 'limited' health literacy and in particular struggle with finding and evaluating information. Delivering a literacy friendly service in pharmacies is important for this 28% so that literacy and numeracy needs of customers are considered and communication is clear and sensitive.

Colleen Dube, Chief Executive Officer, NALA commented, "We are delighted to present Haven Pharmacy with an award for being the first pharmacy group to have all their pharmacies achieve the Crystal Clear mark. This award celebrates the 49 Haven pharmacies all over Ireland who are engaging with customers in a literacy friendly way. This benefits customers' understanding of health information and their taking their medication correctly."

Daragh Connolly, Chairperson of Haven Pharmacy and pharmacist in Dungarvan added, "We are delighted that Haven is the first pharmacy group to have all their pharmacies awarded the Crystal Clear mark. Our pharmacies have found great benefits from applying for the mark, in particular how staff are now more aware of literacy needs and how to respond sensitively to customers. We can be more responsive and inclusive to the communities we serve every day. Staff are using plain English, avoiding jargon and confusing terms and going over medication and dosage to ensure customer is clear."

A local pharmacist said: "Slowing down and taking time to talk to customers to check their understanding, led to less telephone queries afterwards."

**Preliminary findings for Ireland from the new International Health Literacy Survey (2021)**

- A total of 28% people in Ireland have limited health literacy.
- People in Ireland have particular difficulty with evaluating and finding information related to health.
- Having lower levels of health literacy is associated with poorer outcomes related to lifestyle, health status and health and wellbeing, as well as higher use of certain health services.
- Groups that may need help to improve their health literacy include younger people, people who rate their level in society as low, people with financial difficulties, people who rate their health as fair/bad, people with psychiatric or mental health conditions and people with poor social support.

Mairead McCaul, Managing Director, MSD Ireland (Human Health) added, "We congratulate all Haven pharmacies for achieving the Crystal Clear mark as they demonstrate best practice in providing a health literacy friendly service to the public. We are delighted to continue to support the programme as additional pharmacies take the necessary steps to improve the patient communication, experience and understanding."

**New call for applications**

There is currently an open call for applications for Ireland's only health literacy quality mark under the Crystal Clear Pharmacy Programme. There are seven remaining counties who do not have a Crystal Clear pharmacy yet and so we particularly welcome applications from Laois, Leitrim, Longford, Monaghan, Roscommon, Sligo and Wicklow.

The Crystal Clear Pharmacy Programme, Ireland's first health literacy quality mark for pharmacies, was launched in 2015 by NALA, the Irish Pharmacy Union and MSD and supported by Healthy Ireland. To date 105 pharmacies in 19 counties have been awarded the mark. Pharmacies who wish to participate in the Crystal Clear Programme can complete the online audit here www.nala.ie/health-literacy/crystal-clear-mark/.

The Crystal Clear Pharmacy Programme involves pharmacies completing an online audit consisting of 10 questions. These questions look at how they communicate; staff awareness and responding sensitively; their policies and procedures; and how they evaluate and continually improve their service. Pharmacies who pass the audit get the Crystal Clear mark for three years and get a certificate and sticker to display in their pharmacy. You will find the audit here: www.nala.ie/health-literacy/crystal-clear-mark/

# Future of Pharmacy Event

**The future of pharmacy is in your hands – where will you take it?**

Join APPEL on the 19th of October for our first ever virtual careers event!

WHAT TO EXPECT AT FUTURE OF PHARMACIE?

An online careers event for pharmacy students and professionals.

Panel discussions with pharmacy professionals will showcase the varied and exciting career paths for pharmacists. Get inspiration for your future in pharmacy and get the chance to meet your future colleagues!

Exhibition booths will allow organisations to promote their business or practice area to the pharmacists of the future and build their talent pipeline.

Unique networking opportunities for pharmacy students and professionals alike make this an unmissable event!

ellaonepharmacists.ie

# IT'S HER MORNING AFTER


Be her support and ensure she's making an informed choice. No other emergency hormonal contraception (EHC) is more effective than ellaOne®.[1]

REFERENCES:
1. Glasier A et al. Lancet 2010; 375 (9714): 555-62

PRODUCT INFORMATION ellaOne® 30 mg film-coated tablet (ulipristal acetate). Refer to the SmPC for further information. INDICATION: Emergency contraception (EC) within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. DOSAGE: one 30mg tablet taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure. Another tablet should be taken if vomiting occurs within 3 hours of intake. Can be taken at any time during the menstrual cycle. Not recommended for women with severe hepatic impairment. CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients. SPECIAL WARNINGS AND PRECAUTIONS: Occasional use only. Use reliable barrier method after use until next menstrual period. If next menstrual period is delayed >7 days or is abnormal or suggestive symptoms occur then perform pregnancy test. Consider ectopic pregnancy. If pregnancy confirmed, woman should contact their doctor. Concomitant use with EC containing levonorgestrel not recommended. Does not contraindicate the continued use of regular hormonal contraception but reliable barrier method should be used until next menstrual period. Not recommended in severe asthma treated by oral corticosteroids. Concomitant use of CYP3A4 inducers [e.g. barbiturates (including primidone and phenobarbital), phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing Hypericum perforatum (St. John's wort), rifampicin, rifabutin, griseofulvin, efavirenz, nevirapine] not recommended (may decrease efficacy of ellaOne). Long term use of ritonavir not recommended. Not recommended for women who have used enzyme-inducing drugs in the past 4 weeks. Non-hormonal emergency contraception (i.e. a copper intrauterine device (Cu-IUD)) should be considered. Contains lactose. FERTILITY, PREGNANCY AND LACTATION: Not intended for use during existing or suspected pregnancy. Limited human data does not suggest safety concern. Does not interrupt existing pregnancy. No teratogenic potential was observed; animal data insufficient with regard to reproduction toxicity. Marketing Authorisation Holder maintains a pregnancy registry (www.hra-pregnancy-registry.com) to monitor outcomes of pregnancy in women exposed to ellaOne®. Patients and health care providers are encouraged to report any exposure. Ulipristal acetate is excreted in human breast milk; breastfeeding is not recommended for one week after intake. Breast milk should be expressed and discarded. A rapid return of fertility is likely following ellaOne use; regular contraception should be continued or initiated as soon as possible; subsequent acts of intercourse should be protected by reliable barrier method until next menstrual period. UNDESIRABLE EFFECTS: Always consult the SmPC before prescribing. Only the most common side effects and those which are rare but may be serious are listed below. Most commonly reported adverse reactions: headache, nausea, abdominal pain and dysmenorrhea. Common (≥1/100 to <1/10): mood disorders, dizziness, vomiting, abdominal discomfort, myalgia, back pain, pelvic pain, breast tenderness and fatigue. Rare (≥1/10,000 to <1/1,000): ruptured ovarian cyst. RETAIL PRICE: ellaOne 30 mg single film-coated tablet blister pack; € 35.

MARKETING AUTHORISATION HOLDER Laboratoire HRA Pharma, 200 avenue de Paris, 92329 Châtillon, France. Marketed in Ireland by: HRA Pharma UK & Ireland Limited, Haines House, 21 John Street, Bloomsbury, London, WC1N 2BF MARKETING AUTHORISATION NUMBER(S): EU/1/09/522/003. LEGAL CATEGORY: Medicinal product not subject to medical prescription.

Date of last revision of text: May 2019 Unique ID: IE/ELLA/0112

ellaOne® 30 mg
film-coated tablet Ulipristal acetate

**Adverse events should be reported. Reporting forms can be found at www.hpra.ie or email: medsafety@hpra.ie. Adverse events should also be reported to HRA Pharma UK & Ireland limited on Freephone: 1800 812 984 or email med.info.ie@hra-pharma.com**

IE/ELLA/0200 Date of preparation: November 2020

VITABIOTICS

# Vitamin D


SUPPORTED BY MEDIA CAMPAIGN

## Contributes to normal function of the IMMUNE SYSTEM

For more information contact your Valeo Healthcare rep:

Fintan Byrne: 087 647 0764
fintan.byrne@valeofoods.ie

Julie Webster 086 462 1723
julie.webster@valeofoods.ie

Eamonn Connolly 087 238 5648
eamonn.connolly@valeofoods.ie

PSUITDA3SALESWL1E

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

# Vitamin D in childhood- high rates of deficiency in a cohort of Irish Children

School of Medicine

Helena Scully[1], Dr Martin Healy[3], Prof J Bernard Walsh[1], Dr Vivion Crowley[3], Dr Kevin McCarroll[1], Dr Eamon Laird[1,2]
[1] Mercers Institute for Research on Ageing, St James's Hospital, Dublin 8, Ireland
[2] School of Medicine, Trinity College Dublin, Dublin 2, Ireland
[3] Department of Biochemistry, St James's Hospital, Dublin 8, Ireland

**Introduction:** Vitamin D is essential for bone health, including the uptake and metabolism of calcium. Childhood/adolescence are periods of intensive bone growth, with vitamin D deficiency causing improper bone mineralisation, resulting in rickets. Evidence suggests that rickets prevalence is increasing globally[1], with levels in the UK the highest seen in five decades[2]. Vitamin D intakes were inadequate (<5ug/day) in 94% of 600 Irish children age 5-12 years[3] and teenagers (n= 428, 13-18yrs <10ug/day)[4]. The aim is to assess vitamin D status in a sample of Irish children and adolescents (1-17 years)

**Methods:** We selected children (age 1-17 years) from a sample of GP requested 25-hydroxyvitamin D (25(OH)D) tests analysed at St James's Hospital (SJH) between 2014-2020. The SJH catchment area (53°N) includes Dublin City, County and Eastern Leinster. Serum 25(OH)D concentrations were measured by LC-MS/MS. We identified prevalence of deficiency (<30nmol/L) and insufficiency (30-49nmol/L)[5] and stratified by age (<12 years, >12 years), gender and season (Winter; Dec-May vs. Summer; Jun-Nov). Data was analysed using Chi-square and ANOVA tests as appropriate.

**Figure 1. Vitamin D Status in Winter**

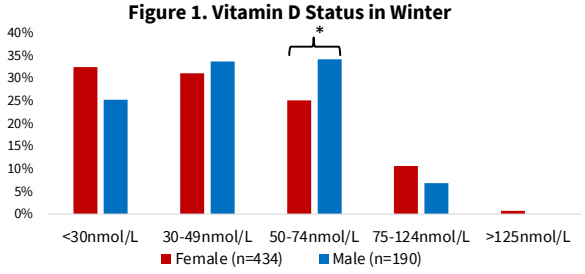
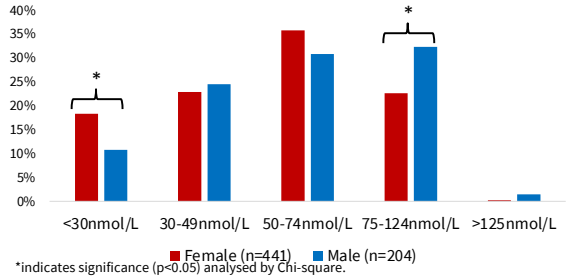



**Figure 2. Vitamin D Status in Summer**




*indicates significance (p<0.05) analysed by Chi-square.

**Results:**

- We identified N=1,269 children, 69% female, 11% under 12.
- Vitamin D deficiency (VDD) was prevalent affecting with 23% and 28% with insufficient vitamin D status.
- The geometric mean 25(OH)D was 43.81 nmol/L.
- Deficiency and insufficiency were more common in winter vs. summer (30% vs 16%, p<0.001), (32% vs. 23%, p<0.001, respectively) **(Figures 1 & 2).**
- Those over 12 years were more likely to be deficient (24% vs. 16%, p=0.033) as were girls vs. boys (25% vs. 18%, p=0.003) **(Figures 3 & 4)**.

**Figure 3. Vitamin D Status in Under 12s**

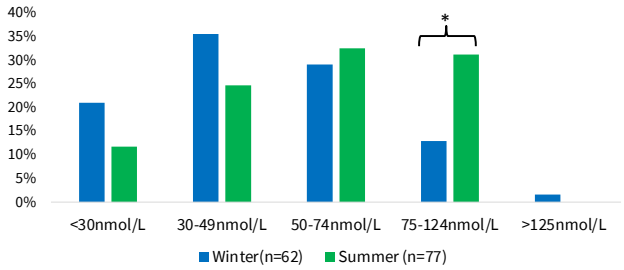
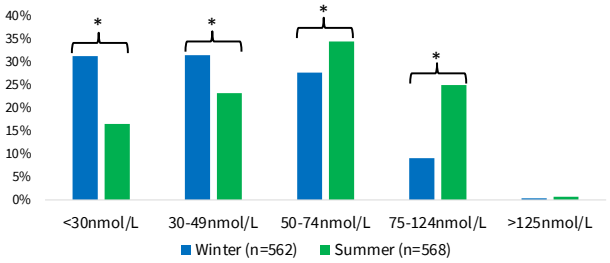



**Figure 4. Vitamin D Status in Over 12s**




*indicates significance (p<0.05) analysed by Chi-square.

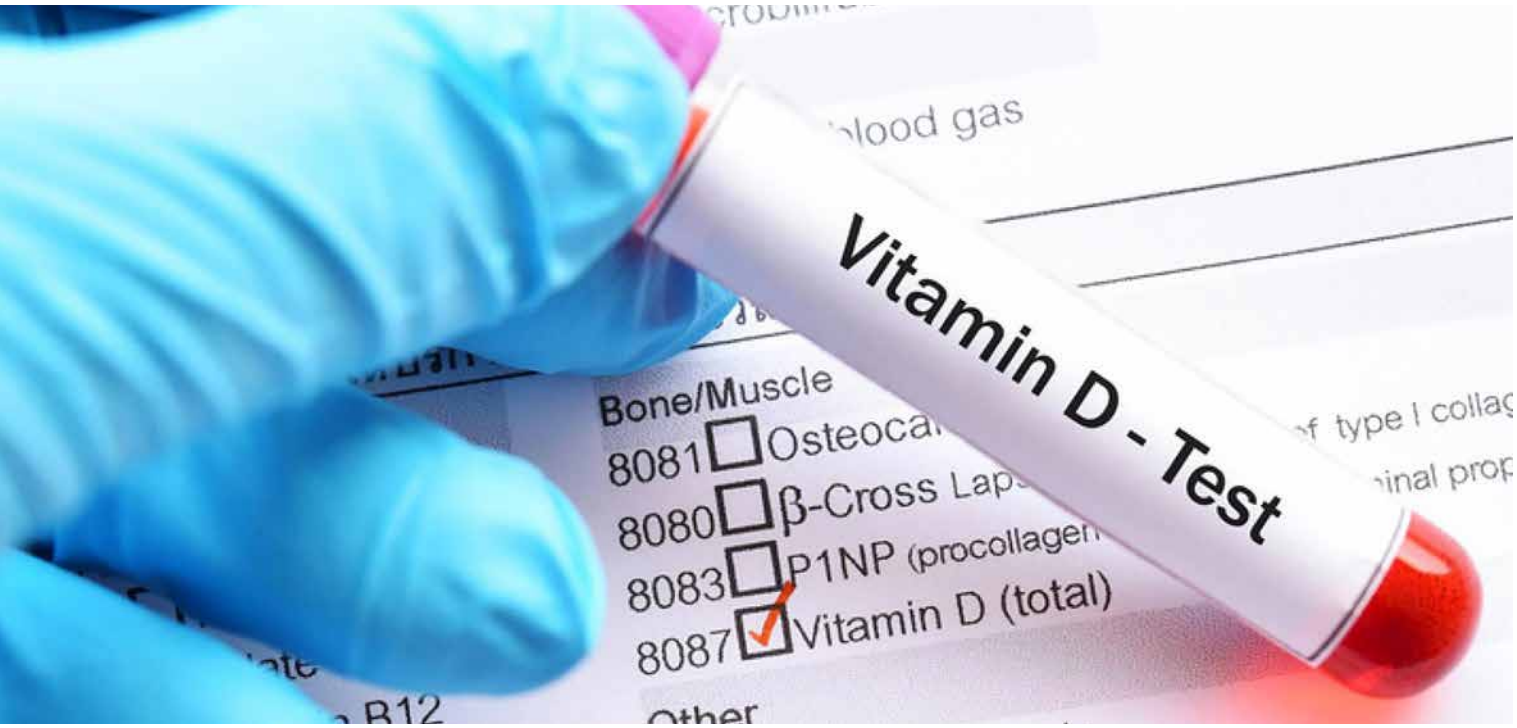
**Conclusion:**

- This is the largest study of vitamin D status in Irish children.
- Low vitamin D status (<50nmol/L) is highly prevalent (51%), with girls, those over 12 years and those assessed in winter most at-risk.
- Irish children's vitamin D status in this study is similar to other EU countries and higher than previously published results in Irish adults[6].
- Public health measures, such as a policy for systematic targeted food fortification, should be considered to address this issue in children.

References:
1. Creo AL, Thacher TD, Pettifor J et al. (2017) *Paediatr Int Child Health 37*(2) 84-98.
2. Goldacre M, Hall N, & Yeates D (2014) *The Lancet 383*(9917) 597-598.
3. IUNA (2019) National Children's Food Survey II: Summary Report.
4. Institute of Medicine (IOM) (2011) Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC: The National Academies Press.; 2011.
5. Irish Universities Nutrition Alliance (IUNA) (2021) The National Teen's Food Survey II
6. Scully H, Laird E, Healy M et al. (2020) *Nutrients 12*(9) 2663.

# Inappropriate and Unnecessary Vitamin D Testing

Trinity researchers have found significant expenditure on vitamin D retesting, yet those who are deficient or most at risk of deficiency (young adults aged 18-39 years) are the least likely to have their vitamin D levels monitored or rechecked in by general practitioners in Dublin.




The study has for the first time, gathered and analysed data on vitamin D retesting. It establishes the need for a better understanding of the role of vitamin D testing in the population and for greater focus to be placed on the monitoring of vitamin D status in particular groups.

The research has identified what proportion of patients are retested, whether this was appropriate, and if vitamin D levels improved after retesting. The team also identified the cost of inappropriate or unnecessary retests.

In recent years, there is greater public awareness of vitamin D, its importance in bone health and potential effects on immunity, the COVID-19 virus and other medical conditions. This has led to a surge in the number of vitamin D tests in Ireland and globally placing increased pressure on healthcare systems.

While there are Irish guidelines for vitamin D testing, there are no clear recommendations as to who should be retested (that is, have repeat tests). This study aimed to identify what proportion of patients are retested, whether this was appropriate, and if vitamin D levels improved after retesting. The cost of inappropriate or unnecessary retests was also identified.

**Key findings**

- One in four patients had their vitamin D retested.
- One in ten tests were requested earlier than recommended, a third were done too frequently and more than half were in patients with adequate vitamin D levels, incurring significant costs.
- While young adults were most likely to have low vitamin D, they were the least likely to have it rechecked.
- Women were also more likely to have repeat tests, however they were less likely to be deficient.
- Discovered that levels of vitamin D deficiency fell considerably between initial and repeat tests, however nearly one in four (23%) still remained deplete after two or more retests.
- Findings suggest that vitamin D testing is common, but the right people are not being tested at the right time.

These findings will help inform guidelines for GPs on vitamin D retesting such as for patients with metabolic bone disorders where monitoring of vitamin D status can be important. The study also suggests that a user-friendly general practitioner (GP) ordering system for vitamin D requests that restricts it to pre-defined criteria, such as limiting retests within 3 months or more than 2 per year, should be considered. By implementing these measures, the number of inappropriate tests and the costs, could be be hugely reduced and the efficiency of the system improved.

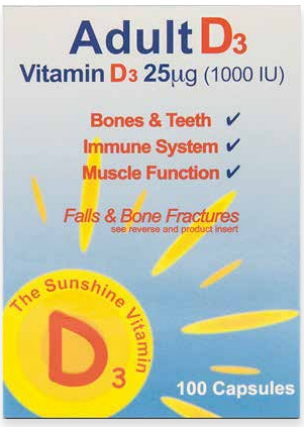
Helena Scully, Mercers Glanbia Bone Research Fellow & Lead Author, MISA Institute, School of Medicine, Trinity College, said, “We have found that one in four patients have their vitamin D frequently checked by their GP, and yet some remain deficient after several tests. Young adults and males were most likely to have low vitamin D but were retested the least. This shows those who are at most risk of vitamin D deficiency are not being assessed, leading to misdirection of resources from those who need it most. Clear guidelines on who should have their vitamin D retested and when are needed to better identify deficiency in the population.

“Instead of going to their GP and requesting multiple vitamin D tests, the public should focus on getting enough vitamin D, via getting good sources of vitamin D in their diets (oily Fish, egg yolk, Fortified milk/dairy products) and by taking a vitamin D supplement (10ug/day for those age 5-65 years).”

Dr Kevin McCarroll, Co-author & Consultant Physician at James’s Hospital and Clinical Senior Lecturer, School of Medicine, Trinity College adds, “The study shows that vitamin D retesting is prevalent yet a large proportion of tests are not being done on the right people or at the right time. It highlights the needs for a better understanding of the role of vitamin D retesting in the population and of the importance of getting enough vitamin D in the diet and /or via supplements rather than having do check levels frequently.”


# BOOST YOUR IMMUNE SYSTEM






For more information contact your Valeo Healthcare rep:

Fintan Byrne: 087 647 0764
fintan.byrne@valeofoods.ie

Julie Webster 086 462 1723
julie.webster@valeofoods.ie

Eamonn Connolly 087 238 5648
eamonn.connolly@valeofoods.ie

# Global Health Issue for the Black Community

New research has recommended that people from the African-Caribbean community should consider increasing their consumption of vitamin D rich foods and taking additional vitamin D supplements, especially in the winter months.

Vitamin D is made when the skin comes into contact with sunshine; however, we can also get vitamin D from our food intake. It has several important functions within the body, but it is primarily known for promoting calcium absorption, which makes it a vital nutrient for bone health.

In a paper published by *The European Journal of Clinical Nutrition*, University of Surrey's researchers conducted a systematic review of the vitamin D and dietary intakes of members of the black community across the globe. The findings suggest that people of African descent should consider taking vitamin D supplements and consume more vitamin D rich foods.

The researchers found that when looking at black individuals who live in low latitude countries (such as Brazil and South Africa), there was vitamin D sufficiency. However, in those who live at higher latitudes, such as in the UK, vitamin D deficiency and insufficiency was common.

The Surrey researchers' findings suggest that awareness of vitamin D deficiency needs to be highlighted in African-Caribbean populations, especially those living in countries like the UK where low dietary vitamin D intake was prevalent.

Rebecca Vearing, PhD research student from the Department of Nutritional Sciences at the University of Surrey, said, "As the majority of our vitamin D comes from exposure to sunlight, for many people getting enough vitamin D may be a real challenge. This research shows that eating a nutritionally balanced diet including foods that provide vitamin D -- such as oily fish, red meat, egg yolk and fortified foods such as breakfast cereals -- and taking regular supplements are key to boosting vitamin D status."

These findings are supported by a second paper from Surrey published by *The Journal of Nutrition*, where researchers studied how vitamin D supplements and sunlight exposure affect the health of Brazilian women living in both the UK and Brazil.*

This first-of-its-kind study examined two groups of the same ethnic identity and sex, living in different countries in an identical way and looked at whether supplements or sunlight altered the vitamin D status of its participants.

Researchers studied 120 healthy Brazilian women in parallel, double-blind, randomised, placebo-controlled trials conducted at different latitudes in Brazil and England. Participants were chosen randomly to receive a daily vitamin D supplement or placebo for 12 weeks during the wintertime.

Researchers found that although vitamin D dietary requirements may vary considerably between participants in each country, a moderate dose of vitamin D supplementation is a remarkably effective strategy for raising and maintaining adequate vitamin D levels over the winter months in both the UK and Brazil.

The participants with the lowest initial vitamin D levels had the most significant increases in response to vitamin D supplements.

Overall, the study found that the effect of vitamin D supplements is not dependent on latitude.

Dr Marcela Mendes, visiting research fellow from the Department of Nutritional Sciences at the University of Surrey, said: "Our research looks at different ethnic groups, and our findings show that people might benefit from increasing consumption of foods that naturally contain vitamin D or are fortified with it, or even taking an additional supplement, in the autumn and winter, regardless of where they live."

## Vitamin D as Cancer Protection

Consuming higher amounts of Vitamin D, mainly from dietary sources, may help protect against developing young-onset colorectal cancer or precancerous colon polyps, according to the first study to show such an association.

The study, recently published online in the journal Gastroenterology, by scientists from Dana-Farber Cancer Institute, the Harvard T.H. Chan School of Public Health, and other institutions, could potentially lead to recommendations for higher vitamin D intake as an inexpensive complement to screening tests as a colorectal cancer prevention strategy for adults younger than age 50.

The authors of the study, including senior co-authors Kimmie Ng, MD, MPH, of Dana-Farber, and Edward Giovannucci, MD, DSc., of the T.H. Chan School, noted that vitamin D intake from food sources such as fish, mushrooms, eggs, and milk has decreased in the past several decades.

The results of the study were obtained by calculating the total vitamin D intake -- both from dietary sources and supplements -- of 94,205 women participating in the Nurses' Health Study II (NHS II). This study is a prospective cohort study of nurses aged 25 to 42 years that began in 1989. The women are followed every two years by questionnaires on demographics, diet and lifestyle factors, and medical and other health-related information. The researchers focused on a primary endpoint -- young-onset colorectal cancer, diagnosed before 50 years of age.

During the period from 1991 to 2015 the researchers documented 111 cases of young-onset colorectal cancer and 3,317 colorectal polyps. Analysis showed that higher total vitamin D intake was associated with a significantly reduced risk of early-onset colorectal cancer. The same link was found between higher vitamin D intake and risk of colon polyps detected before age 50.

# VITAMIN D3

2000IU


*The* **sunshine vitamin**

**Contributes to:**

- maintenance of normal bones
- normal function of the immune system
- maintenance of normal muscle function

**MADE IN IRELAND**

**Food supplements should not replace a varied, balanced diet and a healthy lifestyle.**

Viatris/Mylan Ireland, Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland. **www.viatris.com**
**Date of Preparation:** February 2021 **Code:** COL-2020-0004 v2

VIATRIS

# Impact of Young Pharmacists

A new report to showcase the impact of young pharmacists and pharmaceutical scientists on global health has been published today by the Young Pharmacists Group of FIP.

The publication, entitled "Role of early-career pharmaceutical groups in global health", aims to highlight how youth engagement can contribute to the achievement of the FIP Development Goals and United Nations Sustainable Development Goals.

The report presents the results of a survey on the involvement of individual and early-career pharmaceutical group initiatives together with case studies from early-career pharmaceutical groups in Indonesia, Lebanon, Nigeria, Malaysia and Portugal on emergency, advocacy and Covid-19 response.

"We hope this report will inspire individuals to create their own early-career groups in their countries or regions and we also hope that other groups learn from this report and be influenced to develop their initiatives and share their outcomes and knowledge," FIP President Dominique Jordan says in the foreword.

The YPG is a network of motivated young pharmacists and pharmaceutical scientists within FIP with the objectives of facilitating connections and networking so that new ideas can be shared, and doors to information and new possibilities are opened. Membership is open to individuals under 35 years of age or who have graduated from their first degree in pharmacy or pharmaceutical science within the past five years.

# Increase in Neurological Services delivered Online

A national strategy is required to ensure neurological care service providers are adequately resourced to deliver online services, according to a new report launched recently by the Neurological Alliance of Ireland (NAI).of which the Irish Heart Foundation is a member.

'Looking Beyond Covid-19: Embracing Digital Solutions to Neurological Care' is based on surveys and interviews of service-users and providers about their experiences of delivering online care during the pandemic. It was launched by the Neurological Alliance of Ireland to mark World Brain Day 2021 .

The Report found that neurological care providers are delivering on average 60 per cent of their services online, compared to 8 per cent pre-Covid. However, 47 per cent of patients are not being reached online.

Commenting, Magdalen Rogers NAI Executive Director, said, "The onset of the Covid-19 pandemic saw the beginning of a rapid and unprecedented move to deliver online services and supports across neurological care services. Within a very short timeframe, people with neurological conditions were accessing hospital appointments, physiotherapy sessions, support groups and information through their laptop or smartphone.

"Neurological care providers adapted exceptionally well throughout the pandemic to deliver these services online. However, if online services are to remain, we need a national, coordinated approach to the provision of online healthcare, recognising the resources required in terms of equipment, expertise, and dedicated staffing to provide these services. Up to 50 per cent of patients were not availing of online services. We need to understand and address the barriers that prevent people accessing online care if they want to.

"The Report shows that technological barriers are a real issue for both patients and staff when it comes to delivering online care. Service providers reported a lack of appropriate IT equipment and poor broadband as key factors affecting their ability to deliver online care. This needs to be addressed as part of a new national strategy for the delivery of online neurological care services."

The Irish Heart Foundation is one of a number of NAI members featured in the report which incudes details on the innovative digital methods embraced by NAI members throughout the pandemic to ensure service user needs were being met.

# Meno Active Brought to Market

Ahead of Menopause awareness month (October) Revive Active the award-winning and Irish founded super supplement brand, are pleased to launch their latest innovation Meno Active. After 2 years of research and development, Revive Active are proud to bring to market this unique super supplement scientifically formulated to take during and after menopause.

For most women, menopause is a gradual process; one that encompasses a whole host of physical and physiological changes to the body. On average, menopause happens over 4 years from the date of a women's last period, but many women can experience it for up to 10 years after their last period.

The fact that menopause can last for so long and happens to 50% of the population, it is hard to believe that only recently the conversation about menopause and women's hormonal health in general has opened up across the nation.

Meno Active is formulated with a comprehensive blend of 30 vitamins, minerals, omega 3 DHA, digestive enzymes, plant extracts and strains of live friendly bacteria, all delivered in a unique sachet and capsule combination. These ingredients include: Vitamin B6, which contributes to the regulation of hormonal activity Biotin, Magnesium, Thiamine and Iodine, which contribute to the normal functioning of the nervous system. Omega 3 DHA, which contributes to the maintenance of normal brain function and Vitamin C, which contributes to the reduction in tiredness and fatigue.


Each sachet of ingredients creates a citrus flavoured drink when mixed with water. Each capsule contains 3 plant extracts, Ashwagandha, Sage and Green Tea which can sometimes taste a little bitter in a powder format. That's why they are best swallowed in a capsule with a glass of water.

Price: €59.95 for a 1-month supply

Available to purchase from health food stores, pharmacies and reviveactive.com

# Me Today Launched into Irish Pharmacy

New Zealand skincare and supplement company Me Today Limited has announced its arrival into the Irish market.

Available from pharmacies nationwide from 6th September, Me Today is a premium quality range of supplements and skincare designed with wellness and self-care at its core. Me Today offers an effective cross-category range of health supplements and empowering skincare that can be used by both men and women. All products are created with the aim of being easy to 'shop' for consumers and made with the environment in mind.

The range includes a mix of supplements, which are based on scientific and traditional evidence to support overall wellbeing and to help consumers be on top of their game, naturally. All products are encapsulated in easy to swallow vegetable capsules and are packed in glass vessels for efficacy and environmental reasons.

Me Today Skincare is enriched with essential botanicals, antioxidants and vitamins blended specially to hydrate, protect and comfort your skin. The entire Me Today skincare range is vegan or vegetarian friendly and is made from 93%+ naturally derived ingredients.

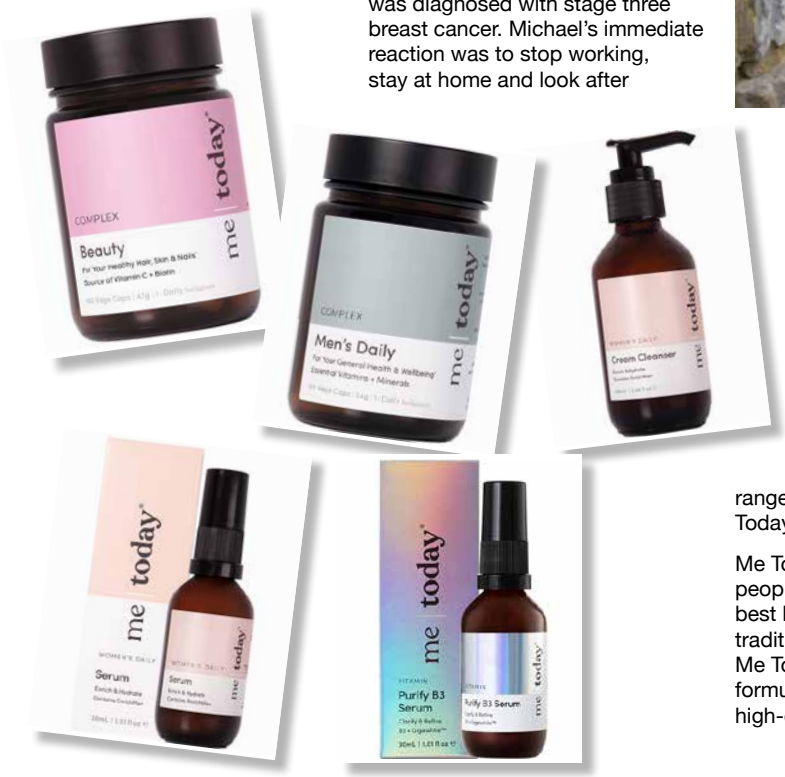
Me Today will be distributed to pharmacies via Uniphar Wholesale Limited. Uniphar operates a fully integrated model with over 280 pharmacies trading under the Allcare, Life and Hickey's pharmacy banners, as well as having access to a network of 1,850 pharmacies across Ireland.

Uniphar Consumer Unit Business Manager, Louise Martin

Speaking about the launch, founder and CEO of Me Today, Michael Kerr says, "We are very excited to see Me Today launch into the Irish market and to provide Irish consumers with a new wellness routine. We have had some great feedback from retailers across the country in terms of the point of difference that our brand offers, the formulations and appearance of the products in-store, so we really look forward to seeing how they are received by both the Irish retailers and the consumers themselves."

Uniphar consumer unit business manager, Louise Martin, says, "We couldn't be more excited to bring this unique New Zealand brand to Ireland. As a beautifully designed, cross-category pharmacy solution, Me Today stands out on shelf and we are confident that it will be well received by our customers."

Me Today was founded by Michael Kerr, along with two others, in 2018 after Michael's wife, Nikki, was diagnosed with stage three breast cancer. Michael's immediate reaction was to stop working, stay at home and look after her. However, Nikki wanted Michael to carry on and ensure he was keeping himself healthy, both mentally and physically, so that he could be there to look after the whole family. So, Michael began to focus on nourishing his body from the inside out. It was through his and Nikki's search for a trustworthy supplement and skincare range that the concept for Me Today was born.




Me Today's mission is to help people feel good while living their best life. Based on science and tradition, every product in the Me Today range is thoughtfully formulated and made using clean, high-quality ingredients.

Despite the challenges faced over the last 16 or so months with Covid-19, Me Today has confirmed that they continue to grow in line with expectations, with annual gross revenue for FY21 being at least $1.4m. As communicated at the Me Today Limited Annual Shareholders Meeting held 25 September 2020, the company will deliver gross run rate revenue of $2m in March 2021 with March revenue a minimum of $166k.

With additional sales from the roll out to Irish retailers and partnerships in Japan and Australia, Me Today expects annual gross revenue for the financial year ending 31 March 2022 to more than double to at least $3m.

# Therapeutic Management of Stress Urinary Incontinence

Written by Linda Kelly RCSN RN and RM(H Dip), RMP, Advanced Midwife Prescriber in Urodynamics and Women's Health at The National Maternity Hospital, Holles Street - David Fitzgerald MPharm MSc (Clinical Pharmacy) MPSI, Chief Pharmacist at The National Maternity Hospital, Holles Street

**Epidemiology and Risk Factors**

The International Continence Society (ICS) defines urinary incontinence (UI) as "the complaint of any involuntary leakage of urine". UI can be categorised into:

1. Stress Urinary incontinence (SUI) - involuntary leakage on effort or exertion or on sneezing or coughing
2. Urge Urinary incontinence- involuntary leakage accompanied by or immediately preceded by urgency
3. Mixed Urinary Incontinence- Involuntary leakage associated with urgency and also exertion, effort, sneezing or coughing[1]

UI is a major clinical problem and can have a profound effect on a woman's quality of life and activities of daily living. It can be physically debilitating and socially isolating which in turn can lead to loss of self-confidence, feelings of helplessness and in some cases depression and anxiety. SUI is the most common type of urinary incontinence in women[2]. The exact incidence of SUI in Ireland is unknown although various sources suggest that it could affect as many as 1 in 3 women. In 2018 it was estimated that there were 164 million individuals worldwide affected by SUI.

The exact pathophysiology of SUI is unknown although it is agreed that lack of urethral support, poor pelvic floor muscle tone, urethral sphincter damage and urethral hypermobility all play a part to varying degrees. Leakage of urine occurs when the pressure in the bladder exceeds the closure pressure of the urethra. This commonly happens during physical activity such as exercise or on coughing, sneezing or laughing[1]. Risk factors for developing SUI include age, obesity, smoking, parity, vaginal delivery, hysterectomy, depression, IBS, sleep apnoea and neurological disorders[3].

**Non-Pharmacological Management**

Women attending with SUI should be advised that non-pharmacological treatment options are the first line of management. Such treatments can improve symptoms but may not cure them. These options include;

1. Lifestyle changes:
   - o Keeping fluid intake to 1500ml-2000mls daily,
   - o Regular voiding (6-8 times daily),
   - o Caffeine avoidance,
   - o Reducing weight,
   - o Avoiding lifting heavy objects,
   - o Avoiding/managing constipation,
   - o Stopping smoking,
   - o Doing lower impact exercises
2. Pelvic floor physiotherapy with a women's health physiotherapist to help optimise the pelvic floor function.
3. Continence pessaries and vaginal/urethral support devices e.g. Contiform® pessary, Diveen® applicator - these are single use or reusable devices which are inserted into the vagina to provide support to the urethra and help reduce leakage of urine.
4. Containment products; some women prefer to use good quality containment products such as the EVB shorts etc. If using containment products it is important to ensure good perineal and personal hygiene to prevent skin breakdown.
5. Surgical options

**Pharmacological Management**

If non-pharmacological treatments do not improve symptoms women should be referred to an appropriate healthcare provider to discuss. Medications are usually considered as adjunctive therapy, since it is difficult to pharmacologically treat the anatomical factors involved in the pathogenesis of SUI. The development of medications to treat SUI has been slow.

Pharmacological management of SUI aims to increase tone in the urethral muscles. Several medications may contribute to increased urethral tone, but lack of efficacy and/or adverse effects have limited their use in practice (see table 1)[4].

In 2004, the combined serotonin and noradrenaline reuptake inhibitor (SNRI) Duloxetine, was licensed in Europe as adjunctive therapy for SUI. Originally licensed as an anti-depressant, Duloxetine acts by increasing the contractile activity in the urethral sphincter[5]. A Cochrane analysis of nine randomised controlled trials (RCT)s comparing Duloxetine to placebo reported the rate of subjective "cure" using 40mg twice daily to be higher than placebo (10.8% vs 7.7%; 95% confidence interval 1.02 – 1.98; p = 0.04). The estimated absolute size of effect was three more patients cured out of every 100 treated. Nausea was the most common adverse event with an incidence of 23 to 25% and was the main reason for discontinuation[6]. UK guidelines recommend offering Duloxetine as a non-routine, second-line treatment for women with SUI who would prefer pharmacological to surgical treatment or are not suitable for surgical treatment[7]. Despite its established efficacy in phase III trials, the Food and Drug Administration (FDA) in the United States did not grant a license for treatment of SUI due to concerns over increased risk of suicide attempts in women prescribed this medication for this indication.

Pelvic floor disorders are more common after menopause. Hence, oestrogen therapy may be of use in treatment of SUI in post-menopausal women with oestrogen deficiency[8]. Meta-analyses rated the evidence for efficacy of oestrogen in treating incontinence as low but well tolerated[9,10]. Current guidelines suggest the use of oestrogen as an adjunct therapy only[9]. A Cochrane review found the route of administration to be important. A worsening of incontinence was reported with systemic administration compared to an improvement using topical administration[11].

**Future Treatments**

Management of SUI is primarily through non-pharmacological treatment and lifestyle changes. There is an urgent need for development of new pharmacological therapies for SUI that are safe, efficacious and well tolerated.

**Useful resources**

www.continence.ie | www.evb.ie
www.ics.org | www.iuga.org
www.iccp | www.iaun.ie
www.oab.ie | www.hse.ie/continence

**References available on request**

Table 1

| Medication | Level of evidence | Grade of Recommendation |
|---|---|---|
| Duloxetine | 1 | B |
| Imipramine | 3 | D |
| Clenbuterol | 3 | C |
| Methoxamine | 2 | D |
| Midodrine | 2 | C |
| Ephedrine | 3 | D |
| Norephedrine (phenylpropanolamine) | 3 | D |
| Oestrogen | 2 | D |

# Invisible pad. Reliable protection.

Does your bladder leak pads need to be thick to protect? **Always Discreet doesn't.** It has a unique core with *RapidDry™ layers* that turn liquid to gel, for strong protection in a pad you barely feel.

## question
your protection

try

# Protecting Immunity for the New School Year

As children and the workforce were gearing up to return to school and work in September in line with the easing of Covid-19 restrictions, community pharmacies across Ireland were ensuring a plethora of OTC products to support parents and families.

Boots Ireland Director of Pharmacy and Superintendent Pharmacist Caoimhe McAuley

It is always around this time of year that pharmacists and pharmacy staff start thinking about how to protect the immunity of their local communities and families to ward off colds, flu and other ailments which for many may have abated as a result of mask wearing and shielding at home.

Whilst our immune system does an incredible job of protecting us from many external factors that can make us sick, there are some simple steps that everyone can take to support and protect the immune system so it can work optimally to protect us all.

Boots Ireland Director of Pharmacy and Superintendent Pharmacist Caoimhe McAuley offers the following advice to set families up for success this September:

**Handwashing for Health**

We have all learnt the virtues of good hand hygiene over the past 18 months and these practices should remain. Handwashing helps to prevent the spread of infectious disease including colds, flus and other easily transmissible viruses, so continuing to remind the whole family to handwash regularly and thoroughly is one of the first defences to protecting the immune system.

Using soap and water should be the first port of call but for those who are frequently out and about and not near a sink, advise them to keep an alcohol based sanitizer in their school or handbag.

**Sleep**

If children, and equally adults, are not getting enough quality sleep, studies have shown that they are more likely to get sick after exposure to a virus. It can also affect how quickly they recover. This is because while we sleep, the immune system releases proteins called cytokines and this process needs to increase for those with an infection.

The right amount of sleep differs by age. A child of primary school age may need ten or more hours sleep. A teenager needs nine to ten hours sleep, whilst an adult needs seven to eight hours sleep.

**Vitamins**

The need for vitamins and supplements differs depending on a family's individual needs.

Vitamin D which is important for bone, teeth and muscle health is a required supplement, particularly as we head into the darker winter months when sunlight is not strong enough to produce vitamin D in skin.

**Exercise**

Getting out for exercise either individually or as a family is another important factor in supporting immunity.

Don't forget that exercise can accumulate and doesn't have to be done in one consecutive time period. Advise parents to try turning the commute to school or the office into a walk or get off the bus or train one or two stops earlier. Create a wallchart of daily challenges for the family such as complete 50 star jumps or see who can do the most squats.

**Stop Smoking**

Quitting smoking has significant immune boosting benefits. Boots Ireland offers a Stop for Good service, a 12-week, three-step programme which includes private and confidential support and advice, and rewards for meeting goals along the way.

## Encourage Kids to be SunSmart

Now that children are back to school, the HSE National Cancer Control Programme and Healthy Ireland are asking parents and guardians to protect children's skin from sunburn, and be SunSmart throughout September - even on cloudy days.

Just three instances of severe sunburn in childhood increases children's risk of developing skin cancer (melanoma) in later life.

Children and young people's skin is very sensitive to ultraviolet radiation (UV) from the sun. Skin damage from UV increases the risk of skin cancer. Children and young people's skin is especially vulnerable to the sun. Using sunscreen, wearing long clothing and a hat all help to protect their precious skin from sunburn.

According to Dr Caitríona McCarthy, Consultant in Public Health Medicine, HSE National Cancer Control Programme, "Playing and spending time outdoors is a fun and vital part of childhood. But remember to protect babies and children's skin from the sun, even on cloudy days. Being SunSmart as a child can help prevent skin cancer in adulthood. The sun's rays continue to be strong enough to cause skin damage throughout September, so be sure to protect your children's skin from the sun for the walk or cycle to school, outdoor sports training and playtime by following the Healthy IrelandSunSmart steps".

Evelyn Cusack, Head of Forecasting at Met Éireann said, "As we look towards the start of meteorological autumn on September 1st, it's important to remember that sunshine can still be strong and damaging during the early autumn months, with higher UV levels bringing the risk of skin and eye damage."Be sure to check the UV index on the Met Éireann app and website and when the UV index is three or higher, remember to follow Healthy Ireland's SunSmart 5 S's advice."

"Osteoarthritis was never going to stop me"

Alex Scott MBE
Ambassador

NEW PACKAGING


CLINICALLY PROVEN TO RELIEVE JOINT PAIN AND IMPROVE MOBILITY

FlexiSEQ

# Love Your Immunity

As cold weather sets in, the incidence of respiratory tract infections will inevitably start to rise. Researchers suggest that this is because inhaling cold air leads to vasoconstriction in the respiratory tract mucosa, and the suppression of local and systemic immune responses.[i]

Written by Medical Director of Healthspan Dr Sarah Brewer

Older people appear to be most at risk of respiratory infections, possibly because increased age is also associated with the development of micronutrient deficiencies from eating less food and absorbing nutrients less efficiently.

Diet should always come first, but taking a multivitamin and mineral supplement to correct these deficiencies may contribute to improved immunity and lower levels of inflammation. This is supported by research from Oregon State University, in which adults aged 55 and over who took a daily multivitamin and mineral supplement for 12 weeks were found to be significantly better at fighting off infections than those taking placebo.

If they did become unwell, their symptoms were less severe and went away more quickly. This meant that the number of illness days in those taking a multivitamin was reduced by nearly 70% during the study period (2.29 days versus 6.43 in those taking placebo).[ii]

**Key vitamins and minerals to support immunity**

**Vitamin C**'s antiviral action comes from stimulating the production of immune factors such as interferon, and suppressing the activation of viral genes.[iii] As an antioxidant, it also helps to neutralise inflammation to reduce symptoms.[iv,v]

Vitamin C is particularly important for those under physical stress, in whom supplements were found to reduce the risk of infection and the severity of cold symptoms.[vi, vii, viii] Taking vitamin C supplements can also reduce asthma attacks associated with respiratory infections – partly through its antiviral action and partly by reducing airway sensitivity.[ix]

**Vitamin D** interacts with receptors on macrophages, B lymphocytes and T lymphocytes to help activate and regulate immune responses.[x, xi] Within the respiratory tract, it also stimulates our production of natural antimicrobial factors such as the antibiotic-like proteins known as defensins.[xii]

Studies involving over 19,000 adults show that having low levels of vitamin D increases the likelihood of developing common cold symptoms by 36% compared to people with high levels. Deficiency was especially harmful for people with lung diseases – lack of vitamin D increased the risk of a respiratory infection 5.6-fold in those with asthma and 2.2-fold in those with chronic obstructive pulmonary disease (COPD).[xiii]

It's therefore not surprising that taking a vitamin D3 supplement was found to reduce the risk of developing a respiratory tract infection (including the common cold, influenza and pneumonia) by a third compared with placebo.[xiv] The benefits were even greater in people with a pre-existing vitamin D deficiency.

**Vitamin B12** is involved in DNA synthesis and immune cell division, and also has a role in modulating cellular responses. Compared with normal controls, people with a vitamin B12 deficiency were found to have decreased numbers of lymphocytes, CD8+ T cells, an abnormally high CD4/CD8 ratio and suppressed NK cell activity, all of which improved with vitamin B12 supplementation.[xv]

**Zinc** has an ability to inhibit viral replication and activate infection-fighting white blood cells (T lymphocytes and natural killer cells).[xvi, xvii] Zinc is also needed by the memory T cells that patrol the body, to mount a rapid response when a previously encountered infection is found. The mineral is also important for resetting immune responses and inflammation once an infection has resolved, to avoid prolonging symptoms.[xviii]

**Plant polyphenols to support immunity**

Antioxidant polyphenols found in fruit, vegetables, herbs and spices have antimicrobial effects that protect plants and, when we consume them, can provide us with similar benefits.

The message to eat 5-a-day is important for general health and immune wellbeing, but the National Diet and Nutrition Surveys show that our fruit and vegetable intake has changed little since 2008: adults have remained at around 4 portions per day and children (aged 11 to 18) at around 3 portions per day.[xix]

Plant-based supplements can therefore supply a useful additional boost.

**Elderberries** were traditionally consumed in the form of jams and syrup to reduce the severity and duration of winter infections. They are now known to be a rich source of antioxidant polyphenols (such as the flavonoid quercetin) and anthocyanins, which contribute to their intense, purple-black colour. Besides the well-known antioxidant and anti-inflammatory activities of polyphenols, some also appear to block viruses from entering cells.[xx]

Elderberries also contain unique 'ribosome-inactivating proteins', which reduce the ability of viruses, fungi and bacteria to make the proteins they need to thrive. , These proteins evolved to protect elder trees from infection, and appear to have similar protective effects against viruses that infect humans.

Elderberry extracts are active against influenza types A and B, including the most virulent strains, and can lessen the severity of influenza symptoms as well as shorten the duration of illness.[xxiii] Recent laboratory studies suggest that elderberry extracts are also active against coronavirus infections.[xxiv] As another benefit, elderberry extracts have an antibiotic-like effect that might help prevent secondary bacterial infections as a complication of 'flu.[xxv]

**Probiotics to support immunity**

Probiotic bacteria such as *Lactobacillus and Bifidobacterium* interact with mucosal immune tissues lining the gut to have a moderating effect on systemic as well as local immunity.[xxvi]

A Cochrane analysis of 12 clinical trials involving 3,720 children and adults found that, compared with placebo, probiotics reduced the chance of experiencing at least one to three acute upper respiratory tract infections by 47%, shortened a cold by 1.89 days and reduced antibiotic prescription rates by 35%.[xxvii]

**Conclusion**

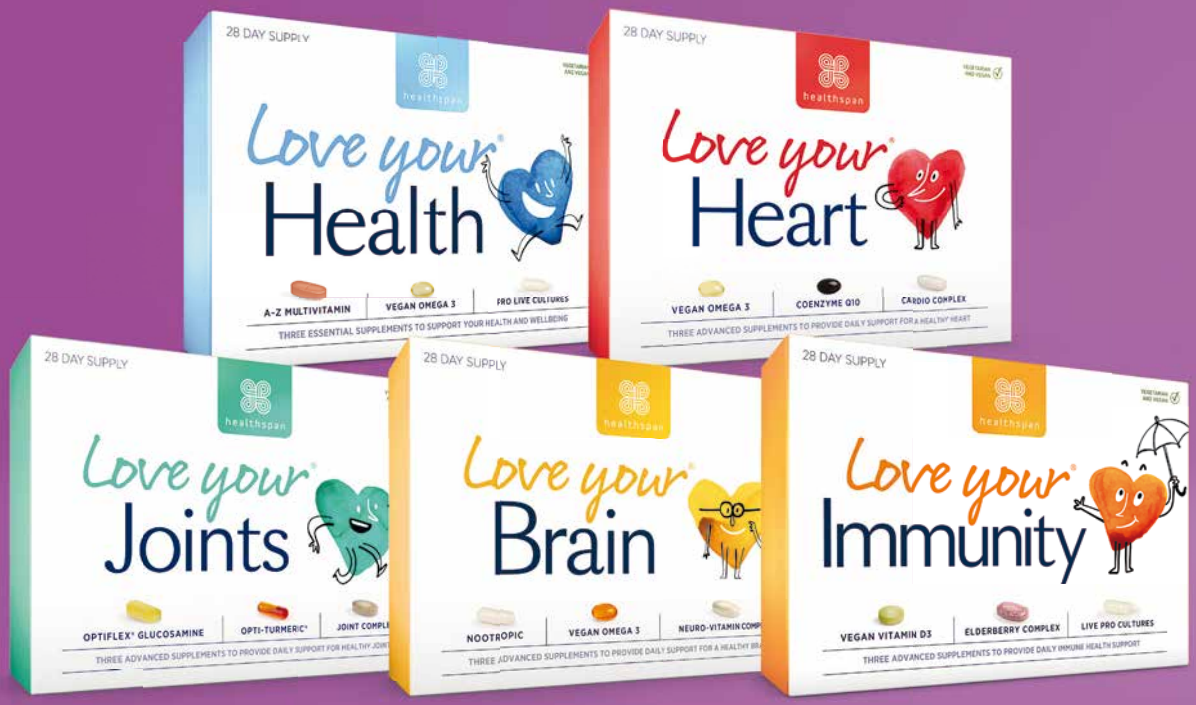
Diet and lifestyle are the most important factors in supporting immunity, but a growing body of evidence suggests that taking certain carefully selected supplements can also help.

Healthspan's Love Your Immunity package provides three important immunity supplements:

- 25mcg vegan vitamin D3 tablet
- an elderberry complex tablet (200mg black elderberry extract, 50mg quercetin, 5mg zinc, 5mcg vitamin B12 and 80mg vitamin C)
- 20 billion live pro bacteria from five well-researched strains of *Lactobacillus acidophilus and Bifidobacterium* lactis in a vegan capsule.

Each pack provides a 28-day supply of these three supplements in convenient daily tear strips to support immune health.

**References available on rtequest**




# *Love your* range

**3 essential supplements in a single pack**

**Handy calendar packaging to improve compliance and repurchase**

**Convenient daily tear strips; perfect for on-the-go**

**Stand-out shelf presence with clearly communicated health benefit**

**73%**

**of consumers are likely to buy from the *Love your* range***

healthspan

*Independent research indicates that on average 73% of existing supplement users are either very likely or fairly likely to buy products from the Love Your range.

Wholefoods
NATURAL FOODS & HEALTHCARE

Contact information:

Wholefoods are an approved wholesaler for Healthspan

Wholefoods Wholesale,
Unit 3, Kylemore Ind Est,
Killen Road, D10

**To order please call:** 01 6262315
sales@wholefoods.ie

# The Future of Pharmacy - Part 4

## The Evolving Role of Supervision in Pharmacy Practice

**LEARNING OUTCOMES**

**At the end of article, you will be able to…**

- Consider how 4Front's 6Ps of Pharmacy Excellence model can equip supervising pharmacists to supervise from an increasingly 'Sage Perspective.'
- Examine evolving challenges supervising pharmacists face
- Discuss 'Supervision' within (and beyond) the Pharmacy context
- Identify personal, professional and business factors that impact the quality of a pharmacist's supervision
- Describe three key supervisor interventions to enhance team performance and patient safety
- Prioritise your next steps towards a becoming an even higher-value supervisor

**INTRODUCTION:**

IPN's Pharmacy Business Excellence Series is for community pharmacists committed to growing their professional and business knowledge and skills to overcome challenges and thrive as a community pharmacist.

IPN is proud to partner with 4Front Pharmacy to bring you the **'IPN/4Front Pharmacy Business Excellence Series.'**

In this series, you will apply 4Front's 6P's of Pharmacy Excellence to navigate the 'Future of Pharmacy.'

**4Front's 6P's of Pharmacy Excellence are**

1. Personal Leadership
2. Professional Practice
3. Person-Centred Care (Patients/Customers/Staff/Other Healthcare Professionals)
4. Products and Services
5. Promotion
6. Prosperity (Profit and Time)

Each month, Rachel Dungan 'The Pharmacist Coach,' guides you to apply **4Front's 6Ps of Pharmacy Excellence Framework** to create your pharmacy future. While Rachel is the creator of this framework and the author of these articles, YOU are the author of your career, your future. The future of pharmacy is in your hands, in your heart, in your head.

Your mission, should you choose to accept it, is to use this framework as a guide to

- (re)activate your inner scientist, so you run the experiments required to take your next bold move towards an ever more compelling future
- develop mastery as you embrace your challenges and opportunities
- take PRIDE in what you do as you create an ever more prosperous future
- equip, enable, engage and empower yourself, your team and your patients to become more proactive about managing your own health and wellbeing.

In Part 1 (July 2021) of 'The Future of Pharmacy,' Business CPD Series, we identified **4Front's Personal Leadership pillar** as the foundation of Pharmacy Excellence. In Part 2 (Aug 2021), we discussed how mastery of **4Front's Promotion pillar** amplifies your ability to promote the value of health, the value of pharmacy, the value of your products and services, and the value of your professional expertise. In Part 3 (Sept 2021) we focused on how **4Front's Professional pillar** can equip us to navigate potential conflicts of interest between personal, professional and business priorities. In this article, we focus on **4Front's People pillar**, in relation to the evolving role of supervision and the supervising pharmacist in pharmacy practice.

Consider how mastery of 4**Front's People pillar** lifts performance in the other 5Ps?

Where is the best place to focus to continually grow and develop yourself and the people you supervise in a way that

- honours the PSI Code of Conduct,
- creates a healthy, positive, learning environment,
- empowers, equips, enables and engages you and your team to be at your best,
- increases your confidence, integrity and reputation, and
- future proofs your career, your business and our profession?

**What evolving challenges do supervising pharmacists face?**

Pharmacy, healthcare systems, patient, staff expectations and the world in which pharmacy services are provided have experienced exponential change since the 'roles and responsibilities of supervising pharmacists' were described in 2008.

From a professional lens,

- governance has evolved to include CPD and Practice Review, Pharmacy Assessment System, the Core Competency Framework, the Code of Conduct and Practice Guidance and Standards on a variety of practice areas and many more.
- The complexity of the medical treatments, the medicine supply chain and the health system in which we operate has deepened.
- We are required to do more with less resources – and this will continue to be so, as the level of human consumption of the Earth's resources is unsustainable.

*The increasing responsibility easily creates overwhelm and begs the question – 'How could one person supervise all this?' What would need to change in how you view 'supervision' that takes into account the complexity of the world in which we operate and the responsibilities we must fulfil?*

From a technology perspective

- Medical information (and misinformation) has been democratised with the internet
- Virtual communication methods are exploding. A decade ago, telephone and fax were the primary virtual methods of virtual communication. Now, electronic prescribing, electronic consultations, social media, digital ordering and booking systems are the norm and rapidly evolving.
- Prescribing, dispensing, medicine supply systems are becoming increasingly automated. Indeed, it is predicted that anything that can be SOP'd, will be automated by the end of the decade.
- According to Hawkins 'This technological revolution will fundamentally alter the way we live, work and relate to one another. In its scale, scope and complexity, the transformation will be unlike anything humankind has experienced before. We do not yet know how it will unfold, but the response to it must be integrated, comprehensive, involving all stakeholders locally, globally, private, public, academia and civil society'.

From a social, economic and ecological lens,

- There is greater demand for pharmacy services as world population and life expectancy continue to grow.
- We are a multi-generational workforce and customer-base, with different values, different priorities, different motivations and high expectations.
- The COVID-19 pandemic has highlighted that we are all inter-dependent and inter-

connected. Our health is not our own. If we want well-being (social, economic, ecological, psychological and physical) we must supervise in a way that creates healthy, rather than toxic, environments.

In summary, we are now living in a volatile, uncertain, complex and ambiguous (VUCA) world.

**What do we mean by 'Super-vision'?**

**According to the** 'Guidance on the Roles and Responsibilities of Superintendent and Supervising Pharmacists.' Published in the IRISH PHARMACY JOURNAL OCTOBER/NOVEMBER 2008 'The Supervising Pharmacist of a practice is the professional who is in whole-time charge of the operation of the pharmacy, and has three years' post-registration experience. This individual is responsible for all operations of the pharmacy, even when absent, and has a reporting relationship to the superintendent pharmacist.'

To expand the perspective of 'super-vision' beyond pharmacy to include 'Supervision in the Helping Professions' (Hawkins and McMahon 2020), supervision is defined as 'a joint endeavour in which the practitioner, with the help of a supervisor, attends to their clients (patients and staff), themselves as part of their client-practitioner relationships and the wider systemic and ecological contexts, and by so doing improves the quality of their work, transforms their client relationships, continuously develops themselves, their practice and the wider profession.'

Integrating the developmental role of educator, with that of being the provider of support to your supervisees and ensuring the quality of your supervisees' work with their clients, colleagues, organisation and organisation's stakeholders is not a simple task. These are weighty responsibilities, for which most of us have not received formal training or supervisory feedback on our role.

Indeed, most of us have not prioritised the absolutely critical discipline of regularly and intentionally creating the space to strategically reflect on the bigger picture in which we operate. We are often too stressed and too busy surviving to lift our heads above the parapet. This short sighted strategy greatly hampers our ability to fulfil our supervision function.

In this context, it is clear that many of the supervision norms of yester-year are no longer fit for purpose. How do we know?

The work culture cultivated in many pharmacies is not yet one that genuinely:

- fosters resilience and wellbeing
- develops a positive, energising, learning culture,
- focuses on the right thing to do (from multiple points of view),
- builds team cohesiveness,
- grows team capabilities and
- delivers significant value and impact for all stakeholders (regulators, business owners, community in which your pharmacy operates, patients and customers, staff, suppliers and partners, future generations, the ecological environment, etc)

Instead, chronic, unrelenting stressors create dysfunction within the helping professions, because when we become stressed, we absorb more disturbance, distress and dis-ease from our environment, colleagues and patients than we are able to process and let go of. Symptoms that you and/or your team members may have exceeded your stress buffering capacity (amplified by COVID pandemic) include:

- **Physical** symptoms such as migraines, difficulty sleeping, over-tiredness, loss of appetite or desire to comfort eat
- **Mental** symptoms such as difficulty concentrating, ruminating on negative thoughts, worry, worst case scenario thining, seeing yourself as a victim (of circumstance, of someone else, of a system)
- **Behavioural** symptoms such as 'compassion fatigue,' (pretending to care or playing the role of carer - but resenting it), avoiding colleagues, situations or patients, turning to drink, over-eating, smoking, gambling or mindlessly scrolling social media, being more accident or mistake prone, increased absenteeism, engaging in destructive interactions such as gossiping, blaming, complaining, hiding mistakes etc.
- **Emotional** symptoms such as wide swings in feelings and moods, not wanting to get up in the morning, feeling anxiety, fear, anger, resentment or guilt in relation to work.
- **Apathy, Boredom and Loss of Interest**, can occur in people whose learning and development journey stagnates (Hawkins). Everything becomes 'same-old, same-old,' with an increasing tendency to treat new colleagues, new patients or new situations as just repeat representatives of those encountered earlier in their career.
- **'The Great Resignation.'** This is a term coined by Anthony Klotz to describe the rise in people who are resigning from their job in 2021. The Great Resignation could be seen as a symptom of dissatisfaction with the status quo and an opportunity to embrace new ways of thinking and being.

One thing is for sure. As supervising pharmacist, you are in a position of influence. This position of influence means that your impact on the systems in which you operate is significant. Your energy, your beliefs, your values, your saboteurs, your strengths and your behaviours infiltrate every aspect of the pharmacy in which you act as supervising pharmacist. The degree to which you and your team flourishes or languishes is largely in your hands. The best supervisors are humble, teachable and always learning.

**What are some factors that affect the quality of your supervision?**

- Your Knowledge of the Legal, Professional and Ethical Frameworks in which we operate
- Your Personal Wellbeing Habits
- Your Mental Fitness and Resources to Sustain Resilience
- The Mental Fitness / Stress / Resilience level of your team
- Your Willingness to Learn new Skills and Unlearn Redundant and Unhelpful ones
- Self-Awareness regarding your own Needs, Emotions, Strengths, Saboteurs, Values, Vision, Motivation, Impact on others
- Your Skill at holding a Wider, Systemic, Big Picture View.
- Your Skill in Reflecting On Your Own Learning and How you are Impacting Your Supervisees. What has worked? What has not worked so well? What different approaches could you try next time?
- Your Support Structures, such as clear feedback loops, dedicated space for both personal and team strategic thinking, dedicated appointments with your own supervisor, coach or mentor. If you don't have the space, time and thinking partner(s) with which to reflect your plans, decisions and actions, the quality of your supervision will suffer.
- Clarity on Measures. You and each of your supervisees must explicitly agree on what success looks like and how value is measured.

As a supervisor, one of your highest value responsibilities is to create a positive, energising, learning culture that empowers, engages, equips and enables your team to do their highest value work, within their scope of practice. Focusing on developing a learning culture will enable you to deepen your supervisory skills, so that you create a virtuous cycle of continuous and never ending improvement. It all starts with restoring and recharging your personal wellbeing foundation, and encouraging your team to join you in your endeavours.

**Your Personal Wellbeing Habits**

Practice physical wellbeing habits, especially while at work and even on a hectic day. Consider how satisfied you are currently with the physical wellbeing habits you and the team you supervise currently practice. From the five focus areas below, choose one in which you and your team could create a habit that would nurture your team's vitality and create a virtuous cycle of wellbeing and high performance?

- **Breathing.** I breathe through my nose 24/7. I do daily breathing exercises and pay conscious attention to when, how, how often I breathe while at work. *One of the most accurate measures of vitality is the BOLT score (Body Oxygen Level Test). A BOLT score of >40 seconds is the goal for optimal energy. The BOLT score takes less than a minute to complete and is done when you are at rest, by holding your breath and timing how many seconds it takes before your body starts giving you the signals that it wants you to breath. The BOLT score is the time taken between holding your breath and those first indications*.
- **Hydration.** I drink at least 1.5L of water throughout the day. *Being **dehydrated** by just 2% impairs performance in tasks that require attention, psychomotor, and immediate memory skills, as well as assessment of the subjective state.*
- **Sleep.** I routinely get sufficient quality and quantity of sleep. I go to bed at the same time and consistently wake up feeling refreshed and alert. *Insufficent sleep can negatively affect mood, attention, memory and health in far-reaching ways*.
- **Eating Well.** I pay attention to the timing, quality and quantity of food I eat. While it is well known that healthy eating is important for health, many supervisors do not realise that the foods we eat have a direct impact on our work performance. *For example, research conducted by scientists at Brigham Young University revealed that employees who rarely ate fruits and vegetables at work were 93% more likely to have a higher loss in productivity*.

- **Movement.** I move my body in ways that deliberately build strength, balance, flexibility and stamina. I do not sit for longer than 45 mins at a stretch. *Employees who had difficulty exercising during the day were 96 percent more likely to have increased productivity loss*.

Practice mental wellbeing habits, proven to enhance you and your team's ability to flourish. The field of Positive Psychology has identified practices across five key areas (PERMA), proven to enhance wellbeing, happiness and performance. By intentionally integrating wellbeing habits into the 'way we do things around here,' you bake mental fitness into your workplace culture. Examples of habits supervising pharmacists and their pharmacy teams have successfully implemented include

- **Positive Emotions.** Barbara Fredrickson's Broaden and Build Theory demonstrates that positive emotions create more positive emotions (and negative emotions create more negative emotions). Evidence based ways to increase positive emotions include to start each day by sharing three things you appreciate/am grateful for with your team. Smile regularly. Practice relaxation techniques (such as yogic breathing, restorative yoga, meditation, guided visualisations). Develop your Sage Powers of Empathise (which encompasses the Values in Action Character Strengths of gratitude, appreciation, love, forgiveness, kindness) and Explore (which encompasses the Values In Action Character Strengths of curiosity, creativity, love of learning).
- **Engagement (state of being in flow).** According to Gallup, engaged employees are "those who are involved in, enthusiastic about and committed to their work and workplace". According to Gallup, in Western Europe, only 10 percent of employees are engaged at work. Luckily, according to Positive Psychology researcher Mihaly Csikszentmihalyi, one way to increase engagement or flow is to regularly provide your supervisees with opportunities to achieve intrinsically rewarding goals, aligned with their strengths, concentrate on a task that balances challenge with skill and provide timely developmental feedback. In addition, according to Forbes, supervisees who feel their voice is heard are x4.6 more likely to feel empowered to perform their best work. On the flip-side 33% of professionals cite boredom as the reason they leave their job. Creating a positive, learning culture of continuous and never ending improvement (CANI) is a powerful antidote to complacency, burnout and boredom.
- **Relationships.** As a supervisor, it is essential to create a positive work environment that brings out the best in everyone, where the team is continually supported to stay ahead of the curve and where everyone feels they want to stay working with you. A key role of a supervisor is to find out what each supervisee enjoys doing, times they have felt most energised at work and to bring in under-utilised strengths. Skilled use of the Positive Intelligence Operating System is a powerful tool to enhance your ability to build healthy relationships. In conflict, it helps you to recognise your own and other's saboteur interference, practice PQ Reps and switch from Saboteur to Sage mode. Character Strengths that are particularly helpful to foster healthy relationships are curiosity, honesty, leadership, teamwork, fairness, social intelligence, self-regulation and kindness. NOTE: Character Strengths are all learnable.
- **Meaning and Purpose.** As a supervisor, your supervisees will be happier, healthier and more productive if you share a common understanding of the purpose of your work, why its important to develop their mental fitness, develop their capabilities, and accomplish team goals, in alignment with your pharmacy's mission, vision and values. Never assume that the purpose is obvious. Always share your why!
- **Achievement.** Supervisees who receive encouraging and honest feedback on their work, feel a sense of accomplishment and success.

**Supervisor Intervention Styles**

According to Heron, a skilled supervisor uses one of six intervention styles to develop their supervisee. As you read them, notice which styles you tend to use the most and which are in your 'stretch' zone. In each case, think of a time when you used that intervention style and it had a positive impact on your supervisee's learning. Now, think of a time when you used that same intervention style and it did NOT have the desired positive impact on your supervisee's development. What was different? The styles are:

- **Prescriptive intervention** – seeks to direct the behaviour of the supervisee. It is usually used when the behaviour is outside the scope of practice of the supervisee E.g. 'Nurofen Plus is a pharmacist-only medicine. The sale of OTC codeine containing products is outside of your scope of practice.'
- **Informative intervention** – imparts knowledge, information or meaning to the supervisee. E.g. 'Paracetamol overdose can cause liver failure'.
- **Confronting intervention** – raise awareness in your supervisee about some limiting attitude or behaviours of which they are usually unaware. E.g. 'Are you aware that not placing the hi-tech order on time resulted in the patient being without their medicine for 4 days?'
- **Cathartic intervention** – enables the supervisee to discharge and process painful emotions, usually anger, grief or fear. E.g. 'You look worried. What concerns or fears do you have about the COVID vaccination service?'
- **Catalytic intervention** – elicits self-discovery, self-directed living, learning and problem solving. E.g. 'What gives you energy? What drains your energy?'
- **Supportive intervention** – affirms the worth and value of the supervisee's person, qualities, attitues or actions. E.g. 'I really appreciate your patience and attention to detail in researching the pros and cons before making a decision.'

In applying any of these intervention styles, 4Front's STEPS Consultation Framework can be a useful feedback framework. **Empathise** is the fulcrum on which the success of your intervention depends. Mutual respect, compassion, empathy, honour and integrity all build trust between you and your supervisees. When the team trusts that you have their best interests at heart, it also increases their willingness to share what is really going on for them, to receive your feedback and act upon your advice. Without a firm foundation of vulnerability based trust, both supervisor and supervisee can end the conversation feeling frustrated, not having identified or solved the real problem.

During developmental conversations between you and your supervisee, it requires that you continually

- master your own Saboteurs, Judgements and Stress
- demonstrate empathy,
- stay curious long enough to understand your supervisee's ideas, concerns and expectations,
- identify the cause the problem or challenge,
- offer a context specific intervention and
- safety net with your supervisee.

**Professional Self-Reflection Questions**

The future of pharmacy and the role of supervising pharmacist is in flux. As you think about pharmacy of the future, consider the following questions with your team, supervisor, coach, mentor or other confidente to help you decide on the most effective path to professional growth and creating value in your pharmacy practice.

- What does 'supervision' mean to you? What does 'supervision' mean to each member of your team? What could 'supervision' mean to you in the future?
- What are examples of you and your team acting in ways that build your mental fitness and embrace continuous and never ending improvement?
- What are examples of negative behaviours you are tolerating? What are the consequences of continuing to tolerate these behaviours?
- What daily habits will you develop within your team, that would support you all to empower, equip, enable and engage one another to achieve your goals?
- What can you do to reduce negative behaviours?
- What potential conflicts of interest are important to identify and proactively address?
- What is work that ONLY you can do (as a pharmacist, as a supervisor)? What activities do you need to stop doing in order to prioritise work that ONLY you can do? What could you delegate? What could you defer? What could you eliminate? What could you automate?
- What conversations / training / upskilling is required to support you and each member of your team to step into your highest value work?

**Summary**

Being a Supervising Pharmacist can be an isolated and lonely job. Many clinicians and supervisors in other helping professions have the routine support of supervisors to help sustain their learning, development, resilience and quality of work throughout what may be a 50 year career. In a world where there is ever more demand, greater expectations of quality and fewer resources, maybe now is a good time to consider how best to provide supervisory support to supervising pharmacists to enable them to be at their best in the supervision of others?

**Next Steps**

- Answer the Self-Reflection questions and record a CPD cycle.
- Dedicate regular time in your diary to pause, reflect and debrief your reflections to ensure that you are not just busy, but intentionally moving in the right direction, for the right reasons.
- Re-read Part 1, 2 and 3 of this Future of Pharmacy series and reflect on how 4Front's 6Ps of Pharmacy Excellence inter-relate for you
- Foster resilience and wellbeing by implementing a structured, systematic way to build you and your team's resilience and mental fitness. As we discussed in Part 1 of this series, there are three core pillars of mental fitness – recognising and intercepting our saboteur voices, habitually building your mental fitness muscles (as opposed to your chronic stress neurocircuitry), and developing access to your Strengths and Sage Brain.
- Engage in ongoing strategies, such as mentoring, coaching or supervision to develop yourself as a supervisor, so you have the reflective space to receive support, knowledge and skills to create and sustain a positive, energising learning environment for your supervisees.

**Further Reading**

- 'Supervision in the Helping Professions' by Peter Hawkins and Aisling McMahon
- 'Positive Intelligence' by Shirzad Chamine
- The Saboteur Assessment at www.positiveintelligence.com/assessments.
- 'Learned Optimism' by Martin Seligman
- Values In Action Strengths Profile http://RachelDungan.pro.viasurvey.org

## RESOURCE ANNOUNCEMENTS

1. As an IPN reader, we invite you to register for FREE pharmacy team training www.4FrontPharmacy.ie. You can also browse our range of online programmes to support you and your team to develop your consultation skills, gain OTC product knowledge and deal with medical emergencies.
2. 4FrontPharmacy Solutions will be hosting two cohorts of the Positive Intelligence® flagship 8-week Mental Fitness Programme specifically for pharmacists and their teams over the coming months. To find out more about how this Programme and Coaching can help you improve morale, wellbeing and team performance, drive your sales and improve patient safety email rachel@racheldungan.com and use the subject line 'IPN Oct 2021.'

**AUTHOR: Rachel Dungan MPSI, ACC.**
Rachel Dungan MPSI, MICF, ACC. Community Pharmacist. Lifestyle Medicine Advisor. Positive Intelligence Certified Coach. European Mentoring & Coaching Council Senior Practitioner. Award-Winning Wellbeing and Leadership Coach known as 'The Pharmacist Coach.' Rachel worked for 20 years as a supervising and superintendent pharmacist. Now, more than ever, her vision is to empower, equip, enable and engage pharmacists and their teams with the knowledge and skills required to focus on what is most important, rediscover joy and happiness and help them build the habits to put their own oxygen mask on first.

She is co-founder of www.4FrontPharmacy.ie.

Its mission is to raise the global standard of pharmacy consultations by empowering pharmacists and their teams to expand their perspective, knowledge and skills to create sustainable health behaviour change.

## Supervising People CPD Cycle

### S
**Self-Appraisal**
**WHAT I intend to learn and why**

I have been recently appointed as Supervising Pharmacist. I want to ensure that I am up to speed on my new role and responsibilities, so I practice legally, professionally and ethically.

### P
**Personal Plan**
**HOW I intend to learn it**

I plan to

- Log into the PSI Website and download any guidance for Supervising Pharmacists
- Speak with colleagues who are working in the role of Supervising Pharmacist
- Speak to the pharmacy owner and superintendent pharmacist to clarify expectations
- Record my learnings in the first few weeks of my new role in this CPD cycle

### A
**Action**
**What I actually did**

- As above PLUS
- I reviewed the IPN business CPD articles on 'the Future of Pharmacy,' because they have an article specifically about the role of Supervision in Pharmacy Practice
- I contacted the article author Rachel Dungan MPSI
- I applied to be a mentee on the IIOP Pharmacist Mentoring Programme

### D
**Document What I have learned specifically**

- I had been taking a very limited, narrow view of the role of supervising pharmacist, but my conversation with Rachel and reading the IPN article expanded my perspective enormously.

### E
**Evaluate ONE example of how I put my learning into practice**

- I had never considered Pharmacy Mentoring until I spoke to Rachel Dungan and she shared her experience as a mentor on the IIOP Mentoring Pilot. The opportunity to have a confidential space to explore my professional practice excites me, so I wrote to the IIOP to submit an expression of interest for their upcoming Mentoring Programme.
- Having spoken to Rachel Dungan, I have enrolled in the 8-Week Positive Intelligence Programme® as a way to enhancing my ability to embrace the challenges and opportunities that being a Supervising Pharmacist will bring.
- I now view my teammates as supervisees, and my primary roles as supervisor are to champion my supervisees growth and development, support them to navigate challenges and enable them to do higher quality and value work, which plays to their strengths. This is far more energising and exciting for me to wrap my head around than the idea of being a 'command and control' style supervisor.

### CCF Domains (and Competencies)

The Pharmacist selected Competencies under the following domains for this CPD Professional Practice (Professional, Ethical, Legal, CPD), 2. Personal Skills (Leadership Skills, Decision Making Skills, Team-Working Skills, Communication Skills)

Contributed by Rachel Dungan MPSI of 4Front Pharmacy. To find out more about how 4Front Pharmacy's Positive Intelligence® Programme and Coaching can help you improve morale, wellbeing and team performance, drive your sales and improve patient safety email rachel@racheldungan.com and use the subject line 'IPN Oct 2021'.

# Where is the Financial Planning Market in 2021?

Financial Advice is a broad term with many definitions and interpretations. Depending on the provider you choose what you receive can vary greatly along with the outcomes. The need for a definitive process to guarantee the best solutions for consumers was the primary driver behind the introduction of the CERTIFIED FINANCIAL PLANNER™ designation in Ireland back in 2010.

Written by Colm Moore, Moore Wealth Management

Colm Moore is a CERTIFIED FINANCIAL PLANNER™ with Moore Wealth Management. They have been advising pharmacists for over 20 years. They can be contacted on 086-8603953 / 051 832839
For more see www.mwm.ie

There are less independent advisers operating over the last 10 years as the market place shrinks and consolidates. The pillar banks, Allied Irish and Bank of Ireland are buying up Goodbody and Davy Stock Brokers respectively. The Canadian owned Irish Life (whose pensions and investments you are sold if you take your advice from the AIB bank channel) are buying multiple medium to large size brokerages to develop their assets under management.

The CERTIFIED FINANCIAL PLANNER™ designation is a standout in the market place for those who wants all options evaluated for them. With an estimated 350 acting independently in Ireland they are highly qualified professionals who ensure you are getting the best advice available from all the options in a process that's accountable and transparent.

A CERTIFIED FINANCIAL PLANNER™ operates with a clearly defined process of developing strategies to help people manage their financial affairs to meet life goals defined as

1. Establish and define the client-planner relationship.
2. Gather client data, including goals.
3. Analyse and evaluate your financial status.
4. Develop and present financial planning recommendations and/or alternatives.
5. Implement the financial planning recommendations.
6. Monitor the financial planning recommendations.

So when you decide you want independent advice what does this mean to you and how does this translate to a financial review once steps one and two above are completed. In practical terms when carrying out a review for any new client we look out for the following

**Life Cover Review**

First you look at what you need for family protection, business protection and loan protection. There are methods to quantify this and one of the most accurate is to map out the impact of the death of either spouse on future cashflows for a defined period which can be to the point for example where any children are through college and independent. Once this figure is established we look at any existing policies to see if they fulfil this need. In the majority of cases we find that clients were over insured and they ended up saving money by cancelling policies. In other cases we find clients are overpaying for cover because due to intense competition in the market place insurance companies are reducing premiums to drive business and increase market share. For nearly 5 years now one of the main insurers in Ireland has had a discount of 15% on life cover premiums. However this discount has to be passed on by the broker which does not happen as much as it should as the commission paid is a function of the premium and discounts impact broker remuneration.

***Takeaway #1 If you have taken out life cover in the last 5 years and not received this discount you should ask your adviser why.***

Business protection has a similar methodology in that you quantify the impact of the death of the business owner and insure accordingly. But what you need to understand is that if the company pays the premium in the event of claim the policy proceeds are paid into the business and not directly to your family. This type of cover is suitable for shareholder protection where a business has more than one owner and the proceeds are used to buy back shares under agreement. It is not suitable where the intention is for the proceeds to go directly to your family as they will have to extract the funds from the company and pay the same taxes as drawing salary. This is a very common problem.

***Takeaway # 2 If you were told to have your business pay for life cover to be more tax efficient are you aware the policy proceeds are going to the company and subject to normal taxation on extraction***

# We've got your future

MOORE
WEALTH MANAGEMENT

## Confidential Pension Second Opinion Service

**We give you the peace of mind that comes with knowing the advice you received was in your best interest**

**As a Certified Financial Planning Firm™ operating at the highest level of accreditation worldwide we will provide you with that reassurance and clarity.**

**www.mwm.ie**

What are we looking for ?

1. **Fees** – Why pay more than you need to? You don't do it for stock in your business so why do it for your pension
2. **Performance** – How does your pension compare to best in class
3. **Risk** – Are you over exposed to risk.
4. **Was there actually financial advice?** - Did you just get sold products or do you have a comprehensive personalized financial plan with full cashflow modelling?

colm@mwm.ie 086 860 39 53 | kieran@mwm.ie 086 380 18 68

**Living Benefits Review**

There should be a clear distinction between life cover (death protection) and living benefits which are income protection and serious illness. Without doubt income protection is the most important cover you can have. Your ability to earn is one of your most valuable unrecognised assets and a culmination of years of hard work, study and determination on your part and needs to be covered. These policies are designed to pay out if you cannot work in your own occupation. With 53% of all claims for this cover relating to psychological and orthopaedic issues in a profession that is high pressure with you on your feet all day there would need to be strong case for not having this. Serious illness is different to income protection in that it pays out a lump sum on diagnosis, typically heart attack, cancer and stroke and works well in tandem with income protection if you are going to be out for a long time or unable to work again.

***Takeaway #3 Medical advances mean you are more likely to survive major illness than die, but what will you do if you are unable to return work and earn a living.***

**Pension Review**

This section has to have a performance and cost review accompanied by full cashflow modelling that shows the future projections of your pension and the drawdown scenarios when you reach retirement age. Your pension is a supremely tax efficient tool for wealth accumulation and cash extraction from a business. It is one asset in your retirement armoury and needs to be overlayed with your other assets and income streams to give you a model of retirement and how best to draw cash. It can make perfect sense to use resources such as the proceeds of business sale first and allow your pension assets to continue to grow in a tax free bubble until needed.

***Takeaway #4 Make sure your pension is projected out to end of life using full cashflow modelling mapping various drawdown scenarios.***

**Investments and Savings Review**

This should look at how you are investing personally held funds and determining if you are optimising the most tax efficient environment for them. Most personally held investments in Ireland suffer from a 1% entry levy, 1-2% annual management charge and 41% tax on gains. This is a tough regime under which to make returns. Options do exist for clients to invest under Capital Gains Tax which removes the 1% entry fee, reduces the annual charge and the tax on gains is at 33% after your annual CGT exemption of €1,270. This is an area that those who have recently profited from the sale of United Drug Shares should be aware of.

This is also the section of the report that ties into inheritance tax planning and it should be quantified if you should be accumulating assets in your children's names to take advantage of the small gift allowance which allows any one person to gift another €3,000 per annum with no tax implications. This has no impact on the current lifetime parent/child threshold of €335,000.

***Takeaway #5 Determine what the best way to accumulate personally held assets and identify the appropriate tax efficient model for holding them.***

**Inheritance Tax Planning**

An often overlooked but key piece of financial planning. This is not on most people's radar but when you realise €335,000 per child is the inheritance tax threshold the problem comes into focus. Only on calculating the combined value of your home, business, pension and investment assets do you realise that everything above €670,000 (two children), €1,005,000 (three children) etc is going to be taxed at 33% that the problem becomes stark and quantifiable. Most pharmacy owners will have businesses valued above this before factoring in other assets.

There are innovative solutions in the market place for this including one of the more ground breaking polices ever launched in Ireland. This policy insures both spouses for the inheritance tax liability. On death the cover amount is received by the estate tax free for settlement of the bill thus leaving all the assets in the children's names. The remarkable part of this policy is that after 16 years if you have not used the policy you are guaranteed that 70% of the premiums paid are returned to you. This is not conditional on anything other than you deciding you want to end the policy. This life cover can protect your family from a substantial tax bill in the medium term while giving you time to plan for alternative ways to reduce the liability. The time provided will give you an idea of whether or not for example if business assets will be passed to children as they grow older which is very tax efficient.

***Takeaway #6 A comprehensive review will identify if this is an issue for you. Seek out a CERTIFIED FINANCIAL PLANNER™ for guidance.***

The advice market is changing and this is natural. The larger players and banks are further developing one size fits all strategies and campaigns. You do not have to fit into one of these templates. The independent financial adviser section of the market place is maintaining its independence and delivering world class solutions for clients.

**BOOTS IRELAND IS CALLING ON PEOPLE TO PARTICIPATE IN A 5KM NIGHT WALK TO RAISE VITAL FUNDS FOR THE IRISH CANCER SOCIETY'S NIGHT NURSING SERVICE**

Boots Ireland has partnered with Muireann O'Connell, Virgin Media TV presenter, to launch its *Boots Night Walk* in aid of the Irish Cancer Society Night Nursing service which provides end-of-life care for people living with cancer in Ireland. The Irish Cancer Society Night Nursing service is free to people who avail of it, and it is funded almost entirely by donations. Boots Ireland has been a proud supporter of the Irish Cancer Society since 2012 and through the support of their colleagues and customers have raised over €2 million for the service so far, equating to over 6,300 nights of care.

Boots Night Walks Campaign ambassador Muireann O' Connell

This year, due to COVID-19 social distancing guidelines and to ensure everyone's safety, Boots Ireland is continuing to do things a little differently. T*he Boots Night Walk* took place on Monday 6th September. You can visit www.bootsnightwalk.com to donate now.

Alongside the walk, Honour Tags are now on sale in Boots stores nationwide for €2. Customers can purchase a tag in honour of someone who has survived or passed away from cancer. The front of the tag allows for the name of the individual with space on the back for a personal message. One metre was walked in honour of that person by members of the Boots Ireland team on September 6th.

All funds raised from the *Boots Night Walk* will go towards the Irish Cancer Society Night Nursing service which provides end-of-life care for cancer patients, allowing them to spend their final days at home surrounded by family and loved ones, as well as giving much needed respite for the family caring for them.

Managing Director at Boots Ireland, Stephen Watkins, said, "Last year, despite the challenges of COVID-19, we raised a phenomenal amount for the Irish Cancer Society's Night Nursing service. This vital service is funded almost entirely by donations, so we would invite the public to get involved by participating and fundraising via BootsNightWalk.com or by purchasing an Honour Tag in any Boots store nationwide. Our entire Boots Ireland team is extremely proud of the work that we have done over ten years to support the Irish Cancer Society and its Night Nurse service, and we would also like to thank the public for continuing to join us on the *Boots Night Walk* again this year as we continue to raise funds for this invaluable service."

**ALZECURE ENTERS THE NEXT DEVELOPMENT PHASE WITH ACD857 FOR ALZHEIMER'S DISEASE**

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of drug candidates for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, has announced that the company has begun a preclinical development phase with the company's drug candidate ACD857.

ACD857 is being developed within AlzeCure's NeuroRestore platform, with the aim of developing symptom-relieving drugs for the treatment of diseases with cognitive disorders. The preclinical development program with ACD857 includes preclinical safety and tolerability studies but also formulation work and stability testing. ACD857 may play a significant role in the treatment of indications in which cognitive functions are impaired, such as Alzheimer's disease.

"We are very pleased to have started the preclinical development with ACD857. We thereby build on the communicated strategy to strengthen the project portfolio with the development of several candidates in parallel and also show AlzeCure's capacity for development and delivery. It's amazing to see how the Discovery and Development organization has performed over the past year with the ability to run both preclinical and clinical programs," said Martin Jönsson, CEO of AlzeCure Pharma AB.

**POSITIVE RESULTS FROM HUMAN CHALLENGE TRIAL OF RSV VACCINE CANDIDATE**

Bavarian Nordic A/S (OMX: BAVA) has announced results from a human challenge trial of the RSV vaccine candidate, MVA-BN® RSV. The phase 2 double-blinded, placebo-controlled trial enrolled healthy adult volunteers, 18-50 years of age who were randomized to receive either a single vaccination of MVA-BN RSV or placebo. Volunteers were challenged intranasally with an RSV type A strain 28 days after vaccination. A total of 61 subjects were evaluable.

The study demonstrated a significant reduction in viral load in vaccinated subjects (n=30) versus placebo (n=31), thus meeting the primary endpoint of this pivotal study. At the same time, the vaccinated subjects showed a significant reduction in clinical symptoms typically associated with RSV infections. The MVA-BN RSV vaccine demonstrated a vaccine efficacy of up to 79% in preventing symptomatic RSV infections.

No vaccine-related serious adverse events were observed, and the vaccine was well tolerated, consistent with the safety profile previously reported in phase 1 and phase 2 clinical studies.

**EUROPEAN COMMISSION IMPLEMENTING REGULATION – GOOD DISTRIBUTION PRACTICE FOR VETERINARY MEDICINAL PRODUCTS**

The Health Products Regulatory Authority (HPRA) wishes to highlight that the European Commission has published an Implementing Regulation on good distribution practice for veterinary medicinal products. It will apply from 28 January 2022, in common with Regulation 2019/6, the New Veterinary Regulation.

The Regulation lays down measures on good distribution practice for veterinary

medicinal products. It applies to manufacturing authorisation holders performing wholesale distribution and to holders of a wholesale distribution authorisation.

It covers the areas of quality management; personnel requirements; premises and equipment; documentation, procedures and record-keeping; operations; complaints, returns, recalls and suspected falsified veterinary medicines; outsourced activities; self-inspections and transport.

For more information, please see the text of the Implementing Regulation, which was published on 29 July 2021. Visit www.hpra.ie for more information.

**ERLEADA®▼ (APALUTAMIDE) APPROVED FOR REIMBURSEMENT IN IRELAND FOR ADULT MEN WITH NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO ARE AT HIGH RISK OF DEVELOPING METASTATIC DISEASE**

The Janssen Pharmaceutical Companies of Johnson & J ohnson has announced that ERLEADA®▼ (apalutamide), a next generation oral androgen receptor inhibitor, has been granted reimbursement in Ireland for the treatment of adult men with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

Data from the pivotal Phase 3 SPARTAN study undertaken ahead of approval, assessed the efficacy and safety of apalutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT in patients with nmCRPC who had a rapidly rising prostate specific antigen (PSA) level despite receiving continuous ADT. Findings from the study showed that apalutamide plus ADT, significantly reduced the risk of developing distant metastasis or death (metastasis free survival [MFS]) by 72 percent, compared to placebo in combination with ADT (HR = 0.28; 95% CI, 0.23-0.35; P < 0.001). The median MFS was improved by over two years (40.5 months vs. 16.2 months) in patients with nmCRPC whose PSA is rapidly rising.

"Delaying the development of metastases is a key goal in the treatment of prostate cancer. Once cancer spreads, it can become less responsive to treatment and can worsen the patient's prognosis," said Professor John McCaffrey, Consultant Medical Oncologist at the Mater Misericordiae University Hospital, Dublin. "The availability of apalutamide, which can increase time without metastases is a welcome development in the treatment of patients with prostate cancer."

"We are delighted with today's announcement of the reimbursement of apalutamide, and we are pleased that we can now offer patients with high risk non-metastatic castration-resistant prostate cancer a new treatment option," said Dr Bríd Seoighe, Head of Medical Affairs, Janssen Science Ireland UC. "At Janssen we believe that bringing medicines to patients at earlier stages of disease is vital to the patients living with the disease and their families."

The most common Grade 3/4 treatment-emergent adverse events in the SPARTAN study were hypertension (14.3 percent vs. 11.8 percent), rash (5.2 percent vs. 0.3 percent), fall (1.7 percent vs. 0.8 percent) and fracture (2.7 percent vs. 0.8 percent). Treatment discontinuation due to adverse events was 11 percent in the apalutamide arm compared to 7 percent in the placebo arm. Rates of serious adverse events were similar in the apalutamide in combination with ADT arm versus placebo in combination with ADT arm (25 percent vs. 23 percent respectively).

**MINISTER FOR HEALTH ANNOUNCES UPDATES TO IRELAND'S COVID-19 VACCINATION PROGRAMME**

The Minister for Health, Stephen Donnelly TD, has announced several updates to Ireland's COVID-19 vaccination Programme. These updates follow recommendations made by the National Immunisation Advisory Committee (NIAC) to the Chief Medical Officer (CMO). The CMO has endorsed these recommendations.

The NIAC has recommended that pregnant women and adolescents from 12 years of age should be offered mRNA COVID-19 vaccination at any stage of pregnancy following an individual benefit/risk discussion with their obstetric care giver.

In April this year, the NIAC had recommended that pregnant women be offered mRNA COVID-19 vaccination between 14-36 weeks' gestation. The NIAC has updated this recommendation based on the growing body of evidence on the safety and effectiveness of COVID-19 vaccination. The evidence clearly indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy.

NIACs updated advice also recommends an extended primary vaccination course with an mRNA vaccine for immunocompromised individuals aged 12 years and older, regardless of whether the initial COVID-19 vaccine they received was an mRNA or an adenoviral vector vaccine.

The third dose of an mRNA vaccine should be given a minimum of two months after the last dose of the primary vaccination schedule.

Minister Donnelly said: "Since the very beginning of this pandemic, we have worked to protect those most at high risk from severe illness and death from COVID-19. I hope that the opportunity to receive a third or booster dose of COVID-19 vaccine dose brings comfort and reassurance to people that these vaccines are very safe and effective and offer protection from COVID-19.

---

**CLONMEL HEALTHCARE ADD MEDITHYME COUGH SYRUP TO THEIR PORTFOLIO OF PRODUCTS FOR COUGH AND COLD**

Clonmel Healthcare is delighted to announce the launch of Medithyme Cough Syrup; a traditional herbal medicinal product containing thyme liquid extract, which can be used as an aid to facilitate coughing up phlegm (expectorant) in productive cough* associated with cold.

Medithyme is a traditional herbal medicinal product. Medithyme is:

✓ Sugar free

✓ Suitable for vegans

✓ Gluten free

The recommended dose is:

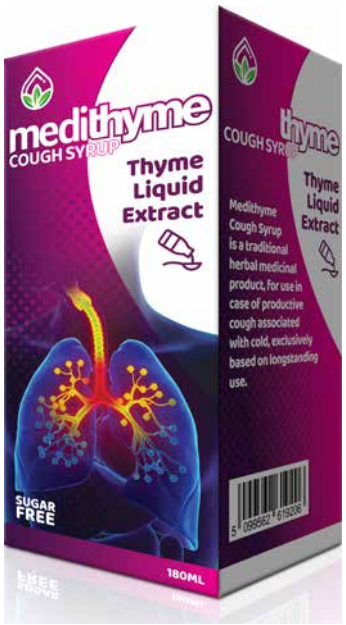
Children from 12 years and adults: 15 ml, 4 times per day.

Shelf life of 5 years; Use within 6 months of opening. Available in 180ml bottle.

A copy of the summary of product characteristics is available upon request. Please contact Clonmel Healthcare on 01-6204000 if you require any additional information.

*Medithyme Cough Syrup is a traditional herbal medicinal product, for use in case of productive cough associated with cold, exclusively based on longstanding use. For supply through general sale.

TR 126/319/001. TR Holder: Clonmel Healthcare Ltd., Clonmel, Co. Tipperary. Date prepared: August 2021. 2021/ADV/MED/083H.



**SKIN CELLS FROM FRONTOTEMPORAL DEMENTIA PATIENTS MAY PROVE USEFUL IN REVEALING DISEASE MECHANISMS AND IN BIOMARKER AND DRUG RESEARCH**

A new study from the University of Eastern Finland suggests that skin fibroblasts from frontotemporal dementia patients may be useful in investigating underlying disease mechanisms as well as in biomarker and drug research.

Frontotemporal dementia (FTD) is the second most common cause of dementia in the working age population. The most common genetic cause of FTD is the C9orf72 hexanucleotide repeat expansion. This expansion is exceptionally common in Finnish FTD patients. Currently, there are no efficient therapies for FTD, it is challenging to diagnose, and the disease mechanisms remain largely unclear.

The new study explored whether skin cells from FTD patients, obtained through skin biopsy performed at Kuopio University Hospital, show specific cell pathological hallmarks or functional alterations compared to healthy individuals, which could promote better understanding of molecular mechanisms of FTD and be useful in the discovery of novel biomarkers or in testing drug effects. Both C9orf72 repeat expansion carriers and patients with sporadic FTD, for whom the underlying cause of disease is unknown, were included in the study.

Cell pathological changes related to the C9orf72 repeat expansion have not been widely described in other cells than neurons so far. In the present study, skin fibroblasts of FTD patients carrying the C9orf72 expansion were found to contain pathological RNA foci in the nuclei, which were derived from the expanded repeat sequence. These findings indicate that skin fibroblasts of carriers of the C9orf72 expansion partially show similar pathological changes to those found in the brain. Thus, patient skin cell cultures may possess potential, for example, as platforms for testing drug effects when screening compounds that could prevent formation of the abnormal RNA foci and the subsequent pathological dipeptide repeat (DPR) proteins derived from these abnormal RNAs.

The brains of FTD patients typically also show other pathological protein inclusions. The present study showed that in the skin fibroblasts of both sporadic and C9orf72 expansion-carrying FTD patients, there were substantially more and larger p62 protein-containing vesicles than in the healthy control fibroblasts. Accumulation of p62 could be a sign of defective ability of the cells to degrade proteins, but defects in the function of the main cellular protein degradation routes, the proteasomes or autophagosomes, were not detected in this study. On the other hand, the present findings raise the question whether the increased number and size of p62 vesicles in skin fibroblasts could be utilised as disease biomarkers in the diagnostics of FTD.

The current study also revealed that skin fibroblasts from both sporadic and C9orf72 expansion-carrying FTD patients displayed a significantly weaker energy metabolism. These changes were detected in assays where the basal respiration and ATP-mediated energy production by the cells' power plants, the mitochondria, were measured. Because the defective energy metabolism and the changes in p62 vesicles were detected in both sporadic and C9orf72 expansion-carrying patients, these pathological alterations may represent common pathological changes in FTD patients regardless of their genetic background.

The changes observed in the skin fibroblasts are partially similar to those observed in the brain of FTD patients.

In the Haapasalo Lab, FTD patient-derived skin cells have also been utilised to generate iPSCs and further differentiated to different types of brain cells, such as neurons and microglia. Examination of these cells is currently ongoing.

The study, published in Molecular Neurobiology, is part of the research activities of the FinFTD Research Network bringing together Finnish basic and clinical FTD researchers. The research, aiming at clarifying disease pathomechanisms and identifying novel biomarker or therapeutic targets using FTD patient-derived skin and neuronal cells, is supported by the FiNeFTD consortium grant from the Academy of Finland to Annakaisa Haapasalo and Prof. Anne Remes from the University of Oulu.

Research article: Leskelä S*, Hoffmann D*, Rostalski H, Huber N, Wittrahm R, Hartikainen P, Korhonen V, Leinonen V, Hiltunen M, Solje M, Remes AM, Haapasalo A. FTLD Patient–Derived Fibroblasts Show Defective Mitochondrial Function and Accumulation of p62. Mol Neurobiol

**ERLEADA®▼ (APALUTAMIDE) APPROVED FOR REIMBURSEMENT IN IRELAND FOR ADULT MEN WITH NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO ARE AT HIGH RISK OF DEVELOPING METASTATIC DISEASE**

The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that ERLEADA®▼ (apalutamide), a next generation oral androgen receptor inhibitor, has been granted reimbursement in Ireland for the treatment of adult men with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

Data from the pivotal Phase 3 SPARTAN study undertaken ahead of approval, assessed the efficacy and safety of apalutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT in patients with nmCRPC who had a rapidly rising prostate specific antigen (PSA) level despite receiving continuous ADT. Findings from the study showed that apalutamide plus ADT, significantly reduced the risk of developing distant metastasis or death (metastasis free survival [MFS]) by 72 percent, compared to placebo in combination with ADT (HR = 0.28; 95% CI, 0.23-0.35; P < 0.001). The median MFS was improved by over two years (40.5 months vs. 16.2 months) in patients with nmCRPC whose PSA is rapidly rising.1

"Delaying the development of metastases is a key goal in the treatment of prostate cancer. Once cancer spreads, it can become less responsive to treatment and can worsen the patient's prognosis," said Professor John McCaffrey, Consultant Medical Oncologist at the Mater Misericordiae University Hospital, Dublin. "The availability of apalutamide, which can increase time without metastases is a welcome development in the treatment of patients with prostate cancer."

"We are delighted with today's announcement of the reimbursement of apalutamide, and we are pleased that we can now offer patients with high risk non-metastatic castration-resistant prostate cancer a new treatment option," said Dr Bríd Seoighe, Head of Medical Affairs, Janssen Science Ireland UC. "At Janssen we believe that bringing medicines to patients at earlier stages of disease is vital to the patients living with the disease and their families."

The most common Grade 3/4 treatment-emergent adverse events in the SPARTAN study were hypertension (14.3 percent vs. 11.8 percent), rash (5.2 percent vs. 0.3 percent), fall (1.7 percent vs. 0.8 percent) and fracture (2.7 percent vs. 0.8 percent). Treatment discontinuation due to adverse events was 11 percent in the apalutamide arm compared to 7 percent in the placebo arm. Rates of serious adverse events were similar in the apalutamide in combination with ADT arm versus placebo in combination with ADT arm (25 percent vs. 23 percent respectively).

**DUPIXENT® (DUPILUMAB) PIVOTAL TRIAL**

A pivotal Phase 3 trial evaluating Dupixent® (dupilumab) for the treatment of children aged 6 months to 5 years with moderate-to-severe atopic dermatitis, a chronic type 2 inflammatory disease, met its primary and all secondary endpoints. The data show adding Dupixent to standard of care topical corticosteroids (TCS) significantly reduced overall disease severity and improved skin clearance, itch, and health-related quality of life measures at 16 weeks compared to TCS alone. Dupixent is the first biologic medicine to show positive results in this young population and remains the only approved biologic medicine in patients 6 years and older with uncontrolled moderate-to-severe atopic dermatitis.

The data reinforce the well-established efficacy and safety profile of Dupixent in other age groups including a lower observed rate of skin infection in the Dupixent group compared with placebo. During the 16-week treatment period Dupixent patients were 50% less likely to experience a skin infection (12% Dupixent, 24% placebo), and the total number of infections was nearly 70% lower (11 Dupixent, 34 placebo). These results add to the extensive LIBERTY AD clinical program – the largest Phase 3 clinical trial program in atopic dermatitis involving approximately 3,500 children, adolescents, and adults to date.

NUTRICIA

# TRUST OUR COMPLETE RANGE TO SUPPORT ALL YOUR COW'S MILK ALLERGY INFANTS

MILD - MODERATE — MODERATE - SEVERE

EXTENSIVELY HYDROLYSED FORMULA (EHF)

AMINO ACID-BASED FORMULA (AAF)


GMS + ACBS Approved


**Pepti 1** From Birth | **Pepti 2** From 6 mths

Ireland's best tasting EHF formula[1]

**Neocate LCP** | From Birth

Ireland's No. 1 Amino Acid-based Formula[2]

**This information is intended for Healthcare Professionals only.**

Neocate LCP, Aptamil Pepti 1 and Pepti 2 are Foods for Special Medical Purposes for the dietary management of cow's milk allergy. In addition, Neocate LCP is also indicated for the dietary management of multiple food protein allergies and for infants who require an amino acid-based formula from birth.They must be used under medical supervision after consideration of all feeding options, including breastfeeding.

Accurate at time of publication: September 2020


**References**

**1.** O'Carroll E et al. (Abstract) Presented at The Nutrition Society Advancing Nutritional Science Spring Conference, Glasgow. 2018. **2.** Nutricia Data on File, 2020


NUTRICIA
LIFE-TRANSFORMING NUTRITION