

CASE STUDY

Sun Pharma

Levoxine (levothyroxine sodium) PBS listing

Case study – Sun Pharma

Situation

- Hypothyroidism affects almost 780,000 Australians, & up to 10 times more women than men
- The condition most commonly afflicts those aged 60+yrs
- If left uncontrolled, hypothyroidism can cause serious health issues, incl. heart disease, infertility, birth complications & nerve damage, & in severe cases, can even prove fatal
- Although there is currently no cure for hypothyroidism, the disorder can be effectively managed with thyroid hormone replacement therapies (HRT)
- HRT replaces the thyroxine the thyroid can no longer make, bringing T4 & TSH levels back to a normal range
- A challenge in managing hypothyroidism is ensuring patient adherence to treatment, with evidence suggesting up 40 to 50% of patients may not take their medication as prescribed
- Therefore, developing an effective management plan tailored to each individual can improve both the short & long-term outcomes, & the quality of life of those diagnosed with hypothyroidism
- The February 1, 2022 PBS listing of Sun Pharma's Levoxine® (levothyroxine sodium) – a thyroid HRT listed for the management of hypothyroidism, & for thyroid tumours responsive to TSH – offers an additional treatment option to those living with this condition, that if left unmanaged, can be life-altering, & debilitating
- Sun Pharma engaged VIVA! Communications to help announce the PBS listing of Levoxine® to medical, industry & consumer media

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Communication objectives

1. To announce the PBS listing of SunPharma's levothyroxine sodium generic to healthcare professional (HCP) & consumer audiences;
2. To heighten awareness of the current unmet need in managing hypothyroidism & the need for improved access to treatment options;
&
3. To partner with endocrinologists & political stakeholders, to strengthen SunPharma's industry reputation

Communications strategy

Coordinate a 3-phased integrated communications campaign comprising:

1. Stakeholder & spokesperson engagement
2. Pre-launch asset development
3. 'Virtual' medical & industry news media launch announcement + targeted 'virtual' consumer news launch media announcement in consultation with the Federal Health Minister's office. teaming with experts & adults living with hypothyroidism

Case study – Sun Pharma

Target audience

1. Medical & HCP community
 - Endocrinologists, general practitioners, pharmacists
2. Consumers – those with a lived experience of hypothyroidism, & their families, loved ones & friends
3. The community at large

Implementation

- Secure x5 of Australia's leading endocrinologists to act as medical & consumer launch campaign spokespeople
 - Dr Ted Wu (Sydney), Dr Kiernan Hughes (Sydney), Dr Monica Wagenaar (Brisbane), Prof Duncan Topliss (Melbourne) & Dr Vijay Panicker (Perth)
- Identify, secure & profile x4 Australian adults with lived experience of hypothyroidism for consumer news media announcement leverage
- Perform Government relations & engage with the Federal Health Minister's office to determine announcement timings
- Coordinate an expert-authored opinion piece in the Medical Journal of Australia's publication – MJA InSight+ – both to strengthen the newsworthiness of the consumer announcement, & to raise awareness of the new product within the medical community

Case study – Sun Pharma

Implementation

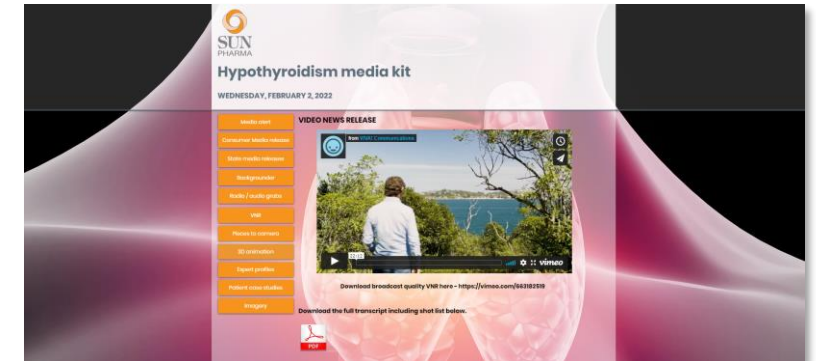
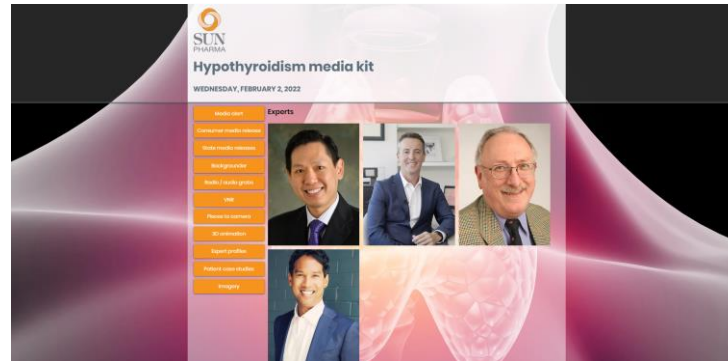
- Produce **campaign key message document (including both consumer and medical messages)** from which all campaign assets would fall
- **Develop a suite of assets for campaign leverage, incl. a medical media kit** comprising:
 - Medical media release
 - 200-word summary
 - Expert profiles x2
 - Product imagery stills
- A comprehensive **consumer news media kit** comprising:
 - National media alert
 - National/NSW, QLD & VIC & WA-specific media releases
 - Hypothyroidism backgrounder
 - Expert profiles x5
 - Patient case studies x4
 - Video News Release (VNR) featuring x2 experts & x1 patient
 - Audio / radio grabs x18 (audio extracted from VNR)
 - Disease & lifestyle-related imagery & hypothyroidism animation



Case study – Sun Pharma

Implementation

- Upload all content to a **digital media kit** –www.thyroidmediakit.com.au – for ease of journalist access
- Set media launch date & refine media strategy in ongoing consultation with Minister's office (Minister chose not to issue a PBS listing product announcement on Levoxine)
- Coordinate a:
 - **'Virtual' medical news media launch announcement from 07:30am on Tuesday, February 1, 2022;** &
 - **Targeted 'virtual' consumer news media launch announcement from 12:01am on Wednesday, February 2, 2022**
- Coordinate interviews with campaign spokespeople upon request
- Monitor stories generated



Case study – Sun Pharma

Challenges

- February 2022 saw 2 additional levothyroxine products introduced to the PBS Levoxine (Sun Pharma) & Eltroxin (Aspen)
 - Both products do not need to be stored in a refrigerator, which was the 'news-hook' for our medical news media announcement – *Australia's first reimbursed thyroid HRT not requiring refrigeration*
- The Minister's office issued an [announcement](#) on January 24, for the February 1 extended listing of Rinvoq® (upadacitinib) for severe atopic dermatitis. On January 31, the Minister announced the February 1 PBS listing of Calquence® for relapsed &/or refractory mantle cell lymphoma (MCL). Aside from these two listings, the Minister's office chose not to perform any other media announcement involving the Feb 1 PBS listings
- Just prior to publication, the MJA Insight+ piece co-authored by Dr Ted Wu & Dr Xi May Zhen, was rejected during the independent peer-review process, with the article deemed too technical for the Insight+ audience comprising mainly GPs. Given the article would no longer be published in time for our announcement, & it was designed to serve a crucial 'news-hook', we had to re-write the consumer materials with a new angle so that they remained newsworthy & ask the co-authors to re-write their piece for publication the following week
- Our primary Sydney patient, Ross, who featured in our VNR, was unable to accommodate any interviews on launch day (Wednesday, February 2, 2022) due to a family emergency

Case study – Sun Pharma

	Online medical + pharma industry media	Consumer TV	Consumer radio	Consumer print & online	Social media	Total
Number of stories	26	48	62	11	22	169
Reach	1,146,944	3,255,498	1,702,236	1,620,139	2,389,737	10,114,554

Key message penetration (consumer media)

The one in 33 Australians living with our nation's most common thyroid disorder – hypothyroidism, or an underactive thyroid – now have access to a new treatment option listed on the Pharmaceutical Benefits Scheme (PBS)	100%
Levoxine® (levothyroxine sodium) is a thyroid hormone replacement therapy listed for the management of hypothyroidism	69%
The PBS listing offers an additional treatment option to those living with this condition, that if left unmanaged/untreated, can be life-altering, and debilitating	90%
Mention of patient or expert quote	95%
Overall key message penetration	89%

Case study – Sun Pharma

MEDICAL MEDIA RELEASE

EMBARGOED: TUESDAY, FEBRUARY 1, 2022

New hormone replacement for hypothyroidism now PBS listed

Australia's first reimbursed thyroid HRT not requiring refrigeration^{1,2}

Australia's first reimbursed bioequivalent thyroid hormone replacement therapy not requiring refrigeration is now listed on the Pharmaceutical Benefits Scheme (PBS).^{1,2}

Levoxine® (levothyroxine sodium) is a thyroid hormone replacement therapy (HRT) listed for the management of hypothyroidism, and for thyroid tumours which are responsive to thyroid-stimulating hormone (TSH).^{1,3}

According to Senior Endocrinologist in the Department of Endocrinology and Diabetes, Alfred Hospital, Professor Duncan Toplis, Melbourne, finding the right treatment option for the one in 33 Australians living with our nation's most common thyroid disorder⁴ is critical to improving patient outcomes.

"Although there is currently no cure for hypothyroidism, the disorder can be effectively managed with thyroid HRT."

"However, given patients with hypothyroidism require life-long, daily medication, there remain challenges with treatment adherence, with up to one in three patients reporting some level of non-compliance."^{1,3} said Prof Toplis.

"If left uncontrolled, or ineffectively managed, hypothyroidism can cause serious health issues, including cardiovascular disease, infertility, neurological and gastrointestinal symptoms, and in severe cases, can rarely even prove fatal."

"Therefore, having a subsidised treatment option not requiring refrigeration, and with distinguishable tablet strengths, offers healthcare professionals additional treatment options that may better suit some patients' needs," said Prof Toplis said.

Thyroid HRT is the primary treatment for hypothyroidism.¹ The principal pharmacological effect of thyroid hormone is to increase the metabolic rate of body tissues.¹ Thyroid hormone is also involved in the regulation of cell growth and differentiation.¹ Thyroxine is the major component of the normal secretion of the thyroid gland, and is therefore, an essential determinant of normal thyroid function.¹

Given many symptoms of hypothyroidism are not specific to the disorder, they can go unnoticed, or be difficult to identify early.^{4,5} The most characteristic symptoms of hypothyroidism include fatigue, unexplained weight gain, intolerance to the cold, hair loss, constipation, change in voice, and dry and itchy skin.^{1,10}

Consultant Endocrinologist at St Vincent's Hospital and Northern Endocrine, Dr Kiernan Hughes, Sydney, said early diagnosis and effective management of hypothyroidism is critical to improving patient quality of life.

"Almost 780,000 Australians are living with hypothyroidism,⁴ those affected often experience extreme exhaustion and other debilitating symptoms that significantly interfere with daily life.

"Concerningly, people living with hypothyroidism may experience significant psychological symptoms, including emotional instability, forgetfulness, and mental slowness.¹

"Furthermore, up to 60 per cent of those affected report some level of depression,"^{11,12} said Dr Hughes.

CONSUMER MEDIA RELEASE

WEDNESDAY, FEBRUARY 2, 2022

FOR IMMEDIATE RELEASE

New treatment option for nation's most common thyroid disorder now listed on PBS

Management and treatment of hypothyroidism not a one-size-fits-all approach – experts advise

The one in 33 Australians living with our nation's most common thyroid disorder¹⁰ – hypothyroidism, or an underactive thyroid – now have access to a new treatment option listed on the Pharmaceutical Benefits Scheme (PBS).¹

Levoxine® (levothyroxine sodium) is a thyroid hormone replacement therapy listed for the management of hypothyroidism, and for thyroid tumours responsive to thyroid-stimulating hormone (TSH).^{1,4}

The PBS listing offers an additional treatment option to those living with this condition, but if left unmanaged, can be life-altering, and debilitating.¹

Coinciding with the PBS listing, experts are today advising there is not a 'one size fits all' approach to the management and treatment of hypothyroidism.¹

According to Staff Specialist Endocrinologist and Director of the Diabetes Centre at the Royal Prince Alfred (RPA) Hospital, Dr Ted Wu, Sydney, having a range of treatment options that Australians living with hypothyroidism can access, helps to ensure they find the right treatment option that best suits their individual needs and lifestyle.

"A challenge in managing hypothyroidism is ensuring patient adherence to treatment. Evidence suggests up to 40 to 50 per cent of patients may not take their medication as prescribed."

"Doctors should consider treatment choice following patient consultation about medication administration, storage, adherence, and lifestyle," said Dr Wu.

"The PBS listing of a new treatment option for Australians living with hypothyroidism will improve treatment access, and choice, for those affected."

Hypothyroidism affects almost 780,000 Australians, and up to 10 times more women than men.⁷ The condition most commonly affects those aged 40 years and over.⁸

Hypothyroidism occurs when the thyroid gland, located near the base of the throat, produces insufficient amounts of the hormone, thyroxine.⁸ Also known as 14, thyroxine plays a key role in controlling metabolism, and can impact heart rate, blood pressure, body temperature and weight.¹

If left uncontrolled, hypothyroidism can cause serious health issues, including heart disease, infertility, birth complications and nerve damage, and in severe cases, can even prove fatal.¹

Although there is currently no cure for hypothyroidism, the disorder can be effectively managed with thyroid hormone replacement therapies (HRT).¹ HRT replaces the thyroxine the thyroid can no longer make, bringing T4 and TSH levels back to a normal range.¹

Many symptoms of hypothyroidism are not specific to the condition, and can therefore, go unnoticed, or be difficult to identify early.¹⁰ explained Consultant Endocrinologist, St Vincent's Hospital and Northern Endocrine, Dr Kiernan Hughes, Sydney.

"The most common symptoms of hypothyroidism include fatigue, intolerance to the cold, unexplained weight gain, constipation, change in voice, and dry and itchy skin."^{1,12}

MEDIA ALERT

EMBARGOED: WEDNESDAY, FEBRUARY 2, 2022

1 in 33 Aussies living with nation's most common thyroid disorder set to access new treatment option

The one in 33 Australians living with our nation's most common thyroid disorder¹⁰ – hypothyroidism, or an underactive thyroid – will this week gain access to a new treatment option listed on the Pharmaceutical Benefits Scheme (PBS).¹

Coinciding with the PBS listing, experts will advise against a 'one size fits all' approach to the management and treatment of hypothyroidism.¹

Hypothyroidism is a life-altering, and debilitating condition¹ affecting almost 780,000 Australians.² The condition affects up to 10 times more women than men,⁷ and most commonly affects those aged 40 years and over.⁸

The most common symptoms of hypothyroidism include fatigue, intolerance to the cold, unexplained weight gain, constipation, change in voice, and dry and itchy skin.¹⁰ with up to 40 per cent of those affected reporting some level of depression.¹²

Concerningly, many symptoms of hypothyroidism can go unnoticed, or be difficult to diagnose.¹² If left uncontrolled, hypothyroidism can cause serious health issues, including heart disease, infertility, birth complications and nerve damage, and in severe cases, can even prove fatal.¹

To learn more, including why it's important to improve treatment access, and choice, for those living with hypothyroidism, see up an interview with a spokesperson below.

EXPERTS AVAILABLE FOR INTERVIEW	
Dr Ted Wu	Staff Specialist Endocrinologist, Director of the Diabetes Centre, Royal Prince Alfred Hospital, SYDNEY
Dr Kiernan Hughes	Consultant Endocrinologist, St Vincent's Hospital and Northern Endocrine, SYDNEY
Dr Monica Wagenaar	Endocrinologist, St Vincent's Private Hospital Northside and Dr Monica Wagenaar Endocrinology, BRISBANE
Prof Duncan Toplis	Senior Endocrinologist, Department of Endocrinology and Diabetes, Alfred Health – the Alfred Hospital, and Professor of Medicine, Department of Medicine, Monash University, MELBOURNE
Dr Vijay Panicker	Endocrinologist, Mount Endocrine and St Charles Gardner Hospital, and Clinical Senior Lecturer, The University of Western Australia, PERTH
AUSTRALIANS LIVING WITH HYPOTHYROIDISM	
Ross, 41	New Dad and high-tech industry worker living with hypothyroidism, SYDNEY
Nicole, 50	Mum, author, and former television news reader living with hypothyroidism, SYDNEY
James, 41	Former sales manager and Bulli (now Illawarra) living with hypothyroidism, BRISBANE
Leigh, 49	Mum-to-three and author living with hypothyroidism, GOLD COAST
DIGITAL MEDIA KIT	https://viva.com.au/4313219
Yours	https://viva.com.au/4313219
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Consumer backgrounder

WEDNESDAY, FEBRUARY 2, 2022

FOR IMMEDIATE RELEASE

About hypothyroidism

About hypothyroidism:

Hypothyroidism is a condition in which the thyroid gland, located near the base of the throat, produces insufficient amounts of the hormone, thyroxine.¹

The thyroid gland is responsible for secreting hormones that regulate the body's metabolic processes, including growth and energy expenditure.¹

There are two main types of hypothyroidism:¹

- Primary hypothyroidism – when the thyroid gland itself becomes diseased; and
- Secondary hypothyroidism – when the pituitary gland – a brain structure that controls the thyroid gland – fails to stimulate the thyroid to produce sufficient hormones.

Iodine-enriched foods are essential for making thyroxine, and iodine deficiency remains the most common cause of hypothyroidism worldwide.^{3,4}

However, with the Australian population exceeding normal daily iodine requirements,⁵ the nation's most common cause of hypothyroidism is Hashimoto's Disease.^{1,4}

Also known as thyroiditis, Hashimoto's Disease is an autoimmune disease in which the body's immune system attacks cells of the thyroid gland.^{1,4}

Hypothyroidism can also be caused by surgery to remove some, or all of the thyroid, as may be the case with thyroid cancer, radiation therapy, treatment for an overactive thyroid (hyperthyroidism), or as a side-effect of some medications, such as those containing lithium.^{1,7}

Prevalence:

- Affecting one in 33 Australians, hypothyroidism is the nation's most common thyroid disorder.¹⁰
- The condition affects up to 10 times more women than men, and is more common in Australians aged 40 years and over.⁸
- Hypothyroidism is seen more in those with existing autoimmune diseases, such as Type 1 diabetes and coeliac disease, and may occur in combination with other hormone (endocrine) conditions.¹
- It is therefore critical to be aware of the signs and symptoms of hypothyroidism, to ensure an accurate diagnosis, and effective management.

Symptoms:

- Many symptoms of hypothyroidism are not specific to the condition, and can therefore, go unnoticed, or be difficult to identify early.^{1,10}
- The most common symptoms of hypothyroidism include fatigue, intolerance to the cold, unexplained weight gain, constipation, change in voice, and dry and itchy skin.^{1,10}
- Neuromuscular symptoms, such as muscle stiffness, weakness, diminished reflexes and cramps, are also common in those living with hypothyroidism.^{8,9}
- Furthermore, hypothyroidism can result in mood changes, including mental slowness and depression, with these psychological symptoms worsening as the condition grows more severe.^{11,12}

Expert profile

WEDNESDAY, FEBRUARY 2, 2022

FOR IMMEDIATE RELEASE

Dr Kiernan Hughes
BMed (Hons), MSc (Pharm Med) CCPU (Ultrasound), FRACP
Clinical Investigator, Garvan Institute of Medical Research and
Consultant Endocrinologist, St Vincent's Hospital and
Northern Endocrine, SYDNEY

Dr Kiernan Hughes is a Clinical Investigator at the Garvan Institute of Medical Research, and a Visiting Medical Officer (VMO) and Consultant Endocrinologist at St Vincent's Hospital, Sydney. He is also a Consultant Endocrinologist at Northern Endocrine, and a Consultant Physician at Griffith Base Hospital, Griffith.

After graduating with a Bachelor of Medicine from the University of Newcastle in 1998, Dr Hughes next completed his Masters of Science specialising in Pharmaceutical Medicine, at the University of Surrey, Guildford, England in 2006.

Dr Hughes specialises in thyroid diseases, pregnancy-related endocrine problems, diabetes, and pharmacotherapy. He is also one of only a few endocrinologists in Sydney who can perform a thyroid ultrasound, and ultrasound-guided biopsies.

Dr Hughes has contributed to multiple peer-reviewed publications, including the recent 'Thyroid disease: Long-term management of hyperthyroidism and hypothyroidism' in early 2021, and helped review the Cancer Council's 'Understanding Thyroid Cancer Booklet'.

end#

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Case study

WEDNESDAY, FEBRUARY 2, 2022

FOR IMMEDIATE RELEASE

Ross, 41 New Dad and high-tech industry worker living with hypothyroidism, SYDNEY

New Dad and high-tech industry worker, Ross, 41, Sydney, was diagnosed with the nation's most common thyroid disease, hypothyroidism, in 2017.

After experiencing an array of symptoms, including food allergies, fatigue, hair loss, and erratic mood changes for some time, Ross chose to visit his GP.

A blood test revealed he had an underactive thyroid, whereby his thyroid gland was producing insufficient amounts of the hormone 'thyroxine', which regulates the body's metabolic processes, including growth and energy use.¹

Ross was subsequently diagnosed with hypothyroidism, and the autoimmune disorder – Hashimoto's Disease, the most common cause of hypothyroidism in Australia.^{1,4}

Today, Ross effectively manages his hypothyroidism with daily hormone replacement medication, following a healthy diet, and exercising regularly.

Given treatment for hypothyroidism is not a 'one-size-fits-all', he is also an advocate for improving patient access to a range of therapeutic options.

This is Ross's story.

In 2015, tech industry worker, Ross, developed new food intolerances and allergies, extreme lethargy, hair loss, and digestive issues. Over time, these symptoms continued, improving a significant fall on Ross' physical and mental health.

"Some days I never occurred at all of once. Instead, they developed gradually, over a long period of time," said Ross.

"Living with hypothyroidism feels like you're constantly wearing heavy armour because you're so tired, which is really challenging to manage, especially with a young family," Ross said.

After experiencing these symptoms for almost two years, Ross' GP ran him through a series of blood tests. In 2017, Ross was finally diagnosed with hypothyroidism and Hashimoto's Disease.

"Before my diagnosis, I'd never heard of hypothyroidism or Hashimoto's Disease. So I had no idea what was causing my symptoms. Originally I thought it was because I was working too hard, or not getting enough sleep, but that wasn't the case," said Ross.



New treatment option for nation's most common thyroid disorder now listed on PBS

Management and treatment of hypothyroidism not a one-size-fits-all approach – experts advise

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

Levoxine

levothyroxine sodium 75 micrograms

200 tablets in 2 bottles, each bottle contains 100 tablets

Each tablet contains: 75 micrograms levothyroxine sodium

AUST R 333028

SUN PHARMA



Dr Ted Wu
Senior Staff Specialist Endocrinologist



Ross, 41
Living with hypothyroidism for the past five years, SYDNEY



Dr Kiernan Hughes
Consultant Endocrinologist, St Vincent's Hospital and Northern Endocrine, SYDNEY



Case study – Sun Pharma

Medical media outcomes (click on publications to view full story)

- [MJA Insight+](#)
- [The Limbic](#)
- [Medical Republic](#)
- [BioPharma Dispatch](#)
- [Pharma in Focus](#)
- [Pharma in the Know](#)
- [Health Industry Hub](#)

Case study – Sun Pharma

7 February 2022
Hypothyroidism: tips for GP management and common pitfalls

GPs represent a cornerstone in the management of primary hypothyroidism, the second most common endocrine disorder that GPs will encounter in their day-to-day practice.

Hashimoto's thyroiditis is generally considered the most common cause of hypothyroidism in [iodine-replete regions, such as Australia](#). In contrast, iodine deficiency is generally the most common cause of hypothyroidism in regions with low levels of dietary iodine.

GPs play a key role in the diagnosis and management of primary hypothyroidism, while referral to an endocrinologist is recommended for secondary hypothyroidism and complex cases of primary hypothyroidism.

There are currently limited Australian data on the prevalence of hypothyroidism, although estimates suggest at least one in 30 adults are living with the condition. Analysis of data from the [Blue Mountains Eye Study \(1997–2000\)](#) found that 4.16% of participants were receiving thyroxine therapy, and unrecognised hypothyroidism (thyroid-stimulating hormone [TSH] levels > 4.5 mIU/L) was reported in 4.1% of participants. These figures are in keeping with more robust international data ([here](#) and [here](#)).

Hypothyroidism can be a subtle disease. For example, patients may not be able to accurately report their history of hypothyroidism, and this is reflected by the fact that 15.3% of current thyroxine users from an [Australian study](#) did not self-report any history of thyroid disease. Hypothyroidism can manifest in a highly variable manner, and apart from thorough history taking, increased awareness among GPs is key to ensuring the timely diagnosis and management of hypothyroidism.

Common symptoms of overt hypothyroidism include lethargy, low mood, weight gain, constipation, cold intolerance, menstrual irregularity, myalgia, muscle weakness, dry skin, thickened/brittle nails, and dry/thinning hair. Women presenting with infertility or subfertility should be assessed for hypothyroidism or autoimmune thyroid disease.

When assessing patients, clinicians should consider factors such as the patient's age, as well as the aetiology, severity and duration of the hypothyroidism, which can all influence the clinical presentation. If there is any diagnostic uncertainty, we recommend referral to an endocrinologist.

Like the symptoms, the signs of hypothyroidism can also be easy to miss. Common clues that point to underlying low thyroid function include thyroid nodules or goitre; cardiovascular signs, such as bradycardia and diastolic hypertension; carpal tunnel syndrome; and the Woltman sign (delayed relaxation phase of the deep tendon reflexes).

Ordering thyroid function tests and looking to the distinctive pattern of raised TSH with low T4 and/or T3 levels confirms the diagnosis. Antithyroid peroxidase (TPO) antibodies and antithyroglobulin (TG) antibodies should be assessed, and will be elevated in most patients with suspected Hashimoto thyroiditis.

Treatment of hypothyroidism is with thyroid hormone replacement, most commonly levothyroxine, which is similar to endogenous T4.

The various levothyroxine preparations are a common source of confusion for GPs and other clinicians. We will provide a brief summary here and the latest Product Information documents can be accessed via the [Therapeutic Goods Administration \(TGA\) website](#).

Australia's first reimbursed thyroid HRT not requiring refrigeration

February 1, 2022

LATEST NEWSBIOPHARMA

Stakeholders have welcomed the reimbursement of the first thyroid hormone replacement therapy not requiring refrigeration.

Sun Pharma's LEVOXINE (levothyroxine sodium) is a thyroid hormone replacement therapy (HRT) listed on the PBS from today for the management of hypothyroidism and for thyroid tumours that are responsive to thyroid-stimulating hormone (TSH).

Thyroid hormone helps to increase the metabolic rate of body tissues. It is also involved in the regulation of cell growth and differentiation.

Many symptoms of hypothyroidism are not specific to the disorder and can go undiagnosed. They include fatigue, unexplained weight gain, intolerance to the cold, hair loss, constipation, change in voice and dry and flaky skin.

Professor Duncan Topliss of the Alfred Hospital said finding the right treatment option for the one in 33 people living with what is Australia's most common thyroid disorder is critical.

"Although there is currently no cure for hypothyroidism, the disorder can be effectively managed with thyroid HRT.

"However, given patients with hypothyroidism require life-long, daily medication, there remain challenges with treatment adherence, with up to one in three patients reporting some level of non-compliance," said Professor Topliss.

"If left uncontrolled, or ineffectively managed, hypothyroidism can cause serious health issues, including cardiovascular disease, infertility, neurological and gastrointestinal symptoms, and in severe cases, can rarely even prove fatal.

"Therefore, having a subsidised treatment option not requiring refrigeration, and with distinguishable tablet strengths, offers healthcare professionals additional treatment options that may better suit some patients' needs."

"Almost 780,000 Australians are living with hypothyroidism," said consultant endocrinologist Dr Kiernan Hughes. "Those affected often experience extreme exhaustion and other debilitating symptoms that significantly interfere with daily life.

"Concerningly, people living with hypothyroidism may experience significant psychological symptoms, including emotional instability, forgetfulness, and mental slowness.

"Furthermore, up to 60 per cent of those affected report some level of depression," said Dr Hughes.

Dr Hughes continued, "In most cases, people diagnosed with hypothyroidism require daily treatment with HRT for the rest of their lives. The dose should be individualised on the basis of clinical response and biochemical tests, to ensure the concentration of thyroxine and TSH remains within the normal range.

"The availability of another thyroid HRT on the PBS provides another treatment option for Australians living with hypothyroidism, and may help minimise the disorder's impact on the daily lives of those affected."

News

Chill comes off PBS listing

Posted 1 February 2022 PM
The first PBS listed thyroid hormone replacement therapy not requiring refrigeration went live today (Tuesday).

Sun Pharma's **Levoxine** will be reimbursed for hypothyroidism, and for thyroid tumours which are responsive to thyroid-stimulating hormone (TSH).

It competes against Aspen's **Oroxine** and **Eutroxsig**, which are PBS listed and require refrigeration. Also, Apsen's **Eltroxin**, which does not require refrigeration but is not PBS listed.

"Almost 780,000 Australians are living with hypothyroidism. Those affected often experience extreme exhaustion and other debilitating symptoms that significantly interfere with daily life," St Vincent's Hospital and Northern Endocrine Consultant Endocrinologist, Dr Kiernan Hughes, said.

"In most cases, people diagnosed with hypothyroidism require daily treatment with HRT for the rest of their lives. The dose should be individualised on the basis of clinical response and biochemical tests, to ensure the concentration of thyroxine and TSH remains within the normal range."

In 2021 Oroxine and Eutroxsig earned \$23.1 million on the PBS/RPBS.

"Given patients with hypothyroidism require life-long, daily medication, there remain challenges with treatment adherence, with up to one in three patients reporting some level of non-compliance," Alfred Hospital Department of Endocrinology and Diabetes Senior Endocrinologist, Professor Duncan Topliss, said.

"If left uncontrolled, or ineffectively managed, hypothyroidism can cause serious health issues, including cardiovascular disease, infertility, neurological and gastrointestinal symptoms, and in severe cases, can rarely even prove fatal.

"Therefore, having a subsidised treatment option not requiring refrigeration, and with distinguishable tablet strengths, offers healthcare professionals additional treatment options that may better suit some patients' needs."

Levoxine is bioequivalent to Oroxine and Eutroxsig and is a a-flagged, meaning it can be substituted at any time of the dispensing process. It is not bioequivalent to Eltroxin, and if a decision is made to switch a patient from Eltroxin to Levoxine dose adjustment may be required.

James Quintana Pearce



HEALTH + WELLNESS

VIVA!

COMMUNICATIONS

a GHMC partner agency

News in brief: New levothyroxine therapy listed on PBS; Osteoporosis researcher awarded Australia Day Honour; Consultants urged to act on junior doctor wage theft

Wednesday, 2 Feb 2022

SHARE

New levothyroxine therapy listed on PBS
The PBS has listed another thyroid hormone replacement therapy and this one doesn't need refrigerating, its manufacturer Sun Pharma says.

From 1 February 2022, Levoxine (levothyroxine sodium) will be subsidised for the management of hypothyroidism, and for thyroid tumours which are responsive to thyroid stimulating hormone.

The 'a-flagged' levothyroxine sodium product is bioequivalent to Oroxine and Eutroxsig and can be substituted with these drugs on a same-dose basis at any stage of dispensing, in line with the PBS treatment criteria. The drug is not bioequivalent to Eltroxin, however, and switching between these drugs should be done with a TSH-monitoring plan and may require dose adjustment, the company said.

Professor Duncan Topliss, Senior Endocrinologist at the Alfred Hospital, Melbourne, said that while the bioequivalent drugs have the same active ingredient and patient outcomes, the new formulation can be stored outside the refrigerator and could offer patients "a little bit more flexibility in terms of ease of use of the drug, perhaps when they're travelling".

As a result, "some people starting out on the agent might prefer to use [Levoxine]" but "I don't think there's a need for patients who are well stabilised on their current brand [of levothyroxine sodium] and don't have any concerns about storage or access to it to change", he told *the limbic*.

Case study – Sun Pharma

CATEGORY
Health & Wellbeing



Health & Wellbeing, Health News, Science

COVID will soon be endemic. This doesn't mean it's harmless or we give up, just that it's part of life

Gold Cross | February 1, 2022



Health & Wellbeing

Long-term fatigue has been 'ignored' in Australia. Will COVID-19 change this?

Gold Cross | February 1, 2022



Health & Wellbeing, Pregnancy & Kids

Go low, go slow: how to rapid antigen test your kid for COVID as school returns



Pharmacy, Business, Health & Wellbeing, Product

New hormone replacement for hypothyroidism now PBS listed

Gold Cross | February 1, 2022

BioPharmaDispatch

Latest News

Guild calls for action as medicine costs continue to rise
The Pharmacy Guild says a new survey shows the cost of prescription medicines is already a barrier to access and that it is only getting worse with the general patient co-payment rapidly approaching \$50.

Biogen appoints new members to its leadership team
The company has appointed three new members to its Australia and New Zealand leadership team to support what it describes as a transformative year.

Australia's first reimbursed thyroid HRT not requiring refrigeration
Stakeholders have welcomed the reimbursement through the PBS of the first thyroid hormone replacement therapy not requiring refrigeration.



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Latest News

GSK takes on asthma rivals
GSK is taking on asthma rivals Sanofi and Novartis with the first directly targeted anti-IL-5 therapy approved for this condition - and the company has PBS listing firmly in its sights.

Chill comes off PBS listing
First non-refrigerated alternative to win reimbursement TODAY

Pharma salaries on the rise
Sign-on payments, bonuses and non-financial perks up for grabs TODAY

Biogen leadership team boom
Two poached execs and one internal promotion ahead of a big year TODAY

Case study – Sun Pharma

Television outcomes (click on publications to view full story)

- [10 News First Sydney](#) – featuring Dr Ted Wu & Nicole Webb
 - Story syndicated on 11 other metro & regional TV stations nation-wide
- [WIN News Hobart](#) – featuring Dr Ted Wu, Dr Kiernan Hughes & Ross
- [10 News First Perth](#) – featuring Dr Ted Wu & Nicole Web
 - Story syndicated on West Digital Television
- [9 News Brisbane](#) – featuring Dr Kiernan Hughes & Jocelyn Carr
 - 9 News story syndicated on 11 regional QLD TV stations
- [9 News Darwin](#) – featuring Dr Kiernan Hughes & Jocelyn Carr
- [WIN News Wagga Wagga](#) – featuring Dr Kiernan Hughes & Ross
 - WIN News story syndicated on 4 regional NSW TV stations
- [Sky News](#) – live interview with Dr Kiernan Hughes
 - Dr Hughes interview also ran on 3 other platforms (Sky News Foxtel, Sky News Digital & Sky News Live – Youtube)
 - Interview was syndicated on 11 other TV stations



Sky News – Weekend Live Interview with Dr Kiernan Hughes

February 6, 2022 – 3:20 PM

Audience: 166,667

Duration: 4:26

Vimeo: <https://vimeo.com/674704720/3b5b998c0b>

Case study – Sun Pharma



10 News First Sydney – Dr Ted Wu & Nicole Webb

Duration: 1:47minutes

Vimeo: <https://vimeo.com/674293174>



WIN News Hobart – Dr Ted Wu, Dr Kiernan Hughes & Ross

Duration: 2:11 minutes

Vimeo: <https://vimeo.com/672965409>



10 News First Perth – Dr Ted Wu & Nicole Webb

Duration: 1:45 minutes

Vimeo: <https://vimeo.com/672964399>



Channel 9 Brisbane – Dr Kiernan Hughes & Jocelyn

Duration: 1:32 minutes

Vimeo: <https://vimeo.com/672962344>



Channel 9 Darwin – Dr Kiernan Hughes & Jocelyn

Duration: 1:38 minutes

Vimeo: <https://vimeo.com/672963162>



WIN Wagga Wagga – Dr Ted Wu, Dr Kiernan Hughes & Ross

Duration: 2:12 minutes

Vimeo: <https://vimeo.com/674244694>

Case study – Sun Pharma

Radio outcomes (click on publications to listen to full story)

- [KIIS 97.3, Brisbane](#) – ran Dr Ted Wu news grabs x2
- [WSFM, Sydney](#) - ran Dr Ted Wu news grabs
- [HOFM Hobart](#) – ran Dr Ted Wu news grabs x3
- [2SM, Sydney](#) – ran Dr Kiernan Hughes news grabs
 - Syndicated on 11 other radio stations
- [2CC, Canberra](#) – ran Dr Ted Wu news grabs
 - Syndicated on 2AC (Canberra)
- [2GB, Sydney](#) – ran Dr Ted Wu news grabs x2
 - Syndicated on 12 other radio stations
- [6PR, Perth](#) – Dr Vijay Panicker interview
- [2GB, Sydney](#) – Dr Vijay Panicker interview
 - Syndicated on 5 radio station in Canberra, Melbourne, Brisbane, Adelaide & Perth



Case study – Sun Pharma

Consumer online & print media outcomes (click on publications to view full story)

- [9news.com.au](https://www.9news.com.au)
- [The Senior](#)
- Take 5 Magazine (print)

Case study – Sun Pharma

News / National

New medication approved to combat hypothyroidism

By Marina Trajkovich | 8:31pm Feb 2, 2022

A new medication developed for people with hypothyroidism could help improve treatment options for hundreds of thousands of Australians struggling with the disease.

One in 33 or 800,000 Australians are currently impacted by the condition, which impacts the thyroid, a butterfly-shaped gland at the base of your neck.

Hypothyroidism affects the thyroid's ability to create the thyroxine hormone, which leads to debilitating fatigue, weight gain, and several other symptoms if left untreated.

Jocelyn Carr thought her never-ending fatigue and brain fog were caused by sickness or stress before a doctor diagnosed her with an underactive thyroid.

"It gets worse as the months progress and you think 'what's wrong with me? Have I got the flu or something?' So I went off to the GP," she said.

The illness, which is more common in women, is often underdiagnosed and can be detected via a blood test.

"Thousands of people who just think too many late nights or too much stress with work when it's not, it could be their thyroid's playing up," Ms Carr said.

READ MORE: [Boris Johnson wins breathing space from 'partygate' woes](#)



Jocelyn Carr found out her never-ending fatigue and brain fog were caused by an underactive thyroid. (9News)

Could you have a THYROID PROBLEM?

The signs to look out for and how to manage it

We all have days when we'd rather veg out on the couch - if you constantly feel lethargic, however, or have low energy for more than a few weeks, it could be related to a thyroid problem.

"Your thyroid produces hormones, which help turn food into energy, so if there's an imbalance in these chemicals, it can wreak havoc on energy levels," says endocrinologist Dr Kiernan Hughes.

"When there's too much of these hormones, it results in a condition known as hyperthyroidism, whereas too little causes hypothyroidism. Both can leave you feeling sluggish, but it's more common with hypothyroidism," naturopath Karina Francois explains.

While the effects of thyroid disorders are unpleasant - unexplained weight gain, swollen legs and brittle nails to name a few - Karina says the majority of conditions can be treated with dietary changes and medication.

"Your body is like a machine. If you put the right fuel into it, it generally responds well," she says.

WHAT EXACTLY IS HYPOTHYROIDISM?

Hypothyroidism, also referred to as an underactive thyroid, is when the thyroid gland doesn't make enough thyroid hormone, which causes your metabolism to become sluggish. It can also affect your body's core temperature, your heart function and how well you burn fat.

Dr Hughes says about 10 per cent of post-menopausal women have thyroid issues, but most instances remain undiagnosed.

"One of the major problems in diagnosing hypothyroidism is that it tends to come on slowly, over many years," he says. "The symptoms are often misdiagnosed or associated with other age-related changes such as menopause."

The most common cause of hypothyroidism is Hashimoto's disease - an autoimmune condition in which immune cells attack the thyroid gland.

"Other reasons why your thyroid may not be working well include not having enough iodine in your diet, but it can also be caused by a viral infection or certain medications," Dr Hughes says.

RECOGNISE THE SIGNS

Women are three times more likely to develop

hypothyroidism than men, and your risk is higher if you have a close family member who has an autoimmune disorder.

Although the symptoms of hypothyroidism can be vague, they often include extreme tiredness, constipation, depression, dry hair and brittle nails, sensitivity to cold weather and facial puffiness.

There may be so many vague symptoms that, Karina says, it's not uncommon for people with hypothyroidism to feel like a completely different person.

"Women often speak about not feeling like themselves," she explains. "They complain about losing the 'spark' and struggling to find motivation in everyday life. They also report feeling unexplained pain, stress and anxiety."

WHEN TO SEE YOUR DOCTOR

One of the biggest challenges of identifying an underactive thyroid is that many of the symptoms mimic other common conditions. If you have any concerns, Dr Hughes recommends you consult your GP to check them out.

"If you're experiencing prolonged symptoms and think it could be related to your thyroid, your doctor can order blood tests to

check your hormone levels," he says. "The initial test checks for thyroid-stimulating hormone (TSH), which evaluates how well your thyroid is working."

If your results are abnormal, your GP will then check what's going on with specific thyroid hormones (T3 and T4) to see if you may have an autoimmune disease, such as Hashimoto's. As a rule, lower than normal T4 levels usually mean you have hypothyroidism.

Karina says certain natural remedies can also play a significant role in improving thyroid function when used in conjunction with conventional medicine.

"With the help of herbal supplements, it's possible to reset your thyroid and see an improvement in as little as a few months," she says.

Just be sure that your doctor is aware of any medications, herbs or supplements you might be taking because some can interfere with how well your body absorbs your prescription medication.

It can wreak havoc on energy levels

HYPERTHYROIDISM VS HYPOTHYROIDISM

Hypothyroidism occurs when your thyroid gland doesn't produce enough hormones for your body's needs. Hyperthyroidism happens when it becomes overactive and makes too much. While symptoms of the conditions vary, both can cause extreme fatigue.

monitored by your GP and the dose reviewed. In addition to taking medication, there are many natural ways to treat or preserve thyroid function, such as eating more iodine-rich foods (sushi with seaweed is ideal) and boosting your dietary intake of trace elements, such as selenium and copper (you'll find them in seafood, shiitake mushrooms, nuts and seeds).

Karina says certain natural remedies can also play a significant role in improving thyroid function when used in conjunction with conventional medicine.

HEALTH + WELLNESS

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18 THE SENIOR Wednesday March 02, 2022

LIFE | HEALTH

Now listen up

NEARLY two-thirds of Australians over 70 have mild to severe hearing loss. And yet only a third of older people who need hearing aids have them, according to the national peak body for deaf and hearing impaired, the Deafness Forum of Australia.

World Hearing Day on March 3 each year raises awareness on how to prevent deafness and hearing loss, and to promote ear and hearing care across the world.

This year's theme is *To hear for life, listen with care*.

If you're concerned you may be losing your hearing, it's important to tackle the problem early. A mild to moderate hearing loss can interfere with easy conversation, especially when there's a lot of background noise. Delaying diagnosis can affect relationships with family and friends.

Ignoring the problem won't make it go away. There's a huge amount of hearing loss help available, including digital hearing aids, which are now much smaller and easier to control. There are also gadgets to make your life easier, including extra-large landlines and mobile phones, amplifiers and flashing doorbells, and even vibrating alarm clocks and watches.

If you're worried about hearing loss, contact your GP, an audiologist or hearing clinic.

If you're suffering from hearing loss, you're not speaking more loudly than usual? Have you noticed lately that you're experiencing hearing loss, tinnitus, or a feeling of fullness or pain in your ears?

If so, you may be suffering from a build-up of ear wax. Earwax specialists in professional earwax removal are a delicate process in which qualified registered nurses use dry micro-suction technology to safely and gently remove the wax.

Some people are more likely to experience a build-up of ear wax than others. This includes people with narrow, hairy or curly ear canals, who wear hearing aids, who use cotton buds or other objects such as ear plugs or ear bud headphones, who work in dusty or dirty environments, or people with a hereditary disposition to wax impaction. Symptoms can include hearing loss, tinnitus, feeling of fullness, itching, pain, discharge, odour or a cough.

Earwax was established in 2016 by registered nurse Lisa Helbridge to provide her clients with a safe and effective earwax removal service. 1800-327-967 www.earwax.com.au

Wax lyrical on ears

IS YOUR family yelling you you're speaking more loudly than usual? Have you noticed lately that you're experiencing hearing loss, tinnitus, or a feeling of fullness or pain in your ears?

If so, you may be suffering from a build-up of ear wax. Earwax specialists in professional earwax removal are a delicate process in which qualified registered nurses use dry micro-suction technology to safely and gently remove the wax.

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Earwax was established in 2016 by registered nurse Lisa Helbridge to provide her clients with a safe and effective earwax removal service. 1800-327-967 www.earwax.com.au

New thyroid meds option

THE one in 33 Australians with hypothyroidism, or an underactive thyroid, now have access to a new treatment option.

Lexosine (levothyroxine sodium) is a thyroid hormone replacement therapy used for the management of hypothyroidism, and for thyroid tumours responsive to thyroid-stimulating hormone.

Staff specialist endocrinologist and director of the Diabetes Centre at St John's Hospital, Prince Alfred Hospital, Dr Ted Wu, said having a range of treatment options helps to ensure people find the right option that best suits their needs and lifestyle.

Hypothyroidism affects most 780,000 Australians, and up to 10 times more women than men - most commonly those 40 plus.

It occurs when the thyroid gland, near the base of the throat, produces insufficient amounts of the hormone thyroxine, which plays a key role in controlling metabolism, and can impact heart rate, blood pressure, body temperature and weight. It can be effectively managed with thyroid hormone replacement therapies.

I want to know more about thyroid conditions? The Australian Thyroid Foundation - [thyroidfoundation.org.au](#)

AUSTRALIAN NEWS HEADLINES

9 NEWS

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We also have regional teams across [New South Wales](#), [Victoria](#) and [Queensland](#), which means nothing gets missed. Our coverage of crime is second to none, with the best court reporters in the business. We are also award-winners for our coverage of the states, holding local governments to account for spending our money, with transport, health and education also hugely important. Check this page for latest Australian news updates and breaking headlines.

New medication approved to combat hypothyroidism

A new medication developed for people with hypothyroidism could help improve treatment options for hundreds of thousands of Australians struggling with the disease.

HEALTH | 12 hours ago

Case study – Sun Pharma

Social media outcomes (click on publications to view post)

Facebook

- [Medical Journal of Australia](#)
- [9News Queensland](#)
 - Syndicated on 9News Adelaide, 9News Perth & 9News Gold Coast Facebook channels

Twitter:

- [Medical Journal of Australia](#)
- [9News Queensland](#)
 - Syndicated on 9News Adelaide, 9News Perth & 9News Gold Coast Twitter channels

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 **The Medical Journal of Australia**
10 February at 20:00 · 🌐

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 **9 News Queensland** ✓
3 February at 03:30 · 🌐

A new medication developed for people with hypothyroidism could help improve treatment options for hundreds of thousands of Australians.
#9News | Nightly at 6pm



9NEWS.COM.AU
New medication approved to combat hypothyroidism
New medication approved to combat hypothyroidism By Marina Trajkovich 8:31pm Feb 2, 20...

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New medication approved to combat hypothyroidism

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