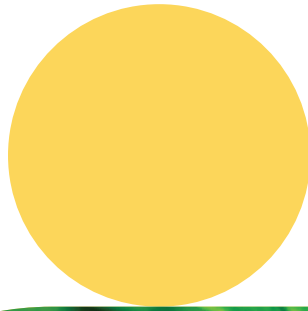


Medicinal cannabis products.



In Australia medicinal cannabis products are used for a range of illnesses and health conditions.

In 2019, of the 2.5 million Australians who used cannabis, 600,000 used it for medicinal purposes only.¹

And access to legal medicinal cannabis products through health care channels continues to increase.

In fact, the Therapeutic Goods Administration has approved access to more than 150,000 medicinal cannabis products through its Special Access Scheme (as of August 31, 2021), with more than 10,000 approved in August alone.²

So, what are legally produced medicinal cannabis products? Is the cannabis used the same as illegally produced cannabis products? What conditions does it potentially help? And can you access it legally?

While there's a lot of interest in medicinal cannabis, there's a lot of confusion about it too.

Here we cut through the confusion by answering some commonly asked questions.



What is medicinal cannabis?

Medicinal cannabis refers to the medical use of chemicals found in the cannabis plant to treat or relieve illness and health conditions.

These chemicals – phytocannabinoids – can be extracted from the cannabis plant or synthetically produced in a laboratory.

Like other medicines, medicinal cannabis products are legally produced to strict quality standards and taken under the supervision of a medical practitioner. These products contain known doses and concentrations of the active

chemicals that are adjusted to increase the therapeutic benefits and reduce potential side effects.³

Illegally produced cannabis, on the other hand, is often taken for enjoyment and to get 'high'.⁴ There's no control over the type or amount of active chemicals in illegally produced cannabis products and it's also illegal in all states and territories in Australia. In the ACT, cannabis is illegal but use and possession of small quantities has been decriminalised.⁵

How do medicinal cannabis products work?

The cannabis plant contains up to 100 different cannabinoids, which act on the body's natural cannabinoid receptors that regulate functions like pain, appetite and memory.⁶

The two main cannabinoids with known therapeutic benefits are:

- delta-9-tetrahydrocannabinol (THC)
- cannabidiol (CBD).⁷

THC is a psychoactive (mind altering) substance that gives people the 'high' when it is smoked or eaten and is why many people use cannabis for non-medical purposes.

CBD is not a psychoactive substance and may moderate the 'high' caused by THC.⁸

THC and CBD can be used together, or independently, in the treatment of different conditions. For example, CBD-only products are often used to manage childhood epilepsy and seizures.⁹

Are medicinal cannabis products safe and effective as medicine?

Legally produced medicinal cannabis products are highly regulated in Australia by the Therapeutic Goods Administration (TGA).

Pharmaceutical quality medicinal cannabis is required by law to meet Australia's high quality and safety standards.

The TGA does not recommend medicinal cannabis products for:

- people with a psychotic or anxiety disorder
- pregnant or breastfeeding women
- people with unstable heart disease.^{10,11}

Most research for medicinal cannabis has focused on five health conditions:

- chronic non-cancer pain
- nausea and vomiting
- epilepsy
- palliative care
- multiple sclerosis.¹²

Ongoing and emerging research into the benefits of medicinal cannabis products for other medical conditions is also underway both here and globally.



What conditions can medicinal cannabis be used for?

In Australia, medicinal cannabis products are not recommended as a first-line treatment for any health condition.

However, medical practitioners can use these products as a possible alternative treatment option when other approved medicines have been unsuccessful.¹³

The TGA provides guidelines to help medical practitioners and their patients make informed decisions about using medicinal cannabis products.¹³

Below is a summary of the clinical uses of medicinal cannabis products by medical practitioners. The information below is not intended as clinical guidelines but rather a summary of how these products are most commonly prescribed:



Condition	Treatment Notes
Chemotherapy-induced nausea and vomiting	High-THC products can be effective but should only be used if newer standard treatments have failed. ¹⁴
Epilepsy in children	High-CBD (CBD-only) products have shown positive results in treating drug-resistant epilepsy and are TGA recommended for use alongside existing anti-epileptic drugs. ¹⁵
Chronic non-cancer pain	Medicinal cannabis products can complement traditional treatment in relieving pain in some patients. Potential drug interactions can occur with other pain medication. ¹⁶
Multiple sclerosis (MS)	Combined CBD:THC products may help relieve MS-related pain, reduce muscle spasticity and improve quality of life. To date, no studies have compared cannabinoids with standard MS treatments. ¹⁷
Palliative (end-of-life) care	Medicinal cannabis products are reserved for patients who don't respond to standard treatment. Potential drug interactions can occur with chemotherapy and other drugs used in palliative care. ¹⁸
Cancer-related anorexia	Medicinal cannabis products are only recommended if standard treatment has failed. ¹⁹

Additional conditions which medicinal cannabis products have been prescribed to treat can be found on the TGA [website](#). Research trials are also underway in Australia for treating insomnia and Tourette syndrome.

What are the side effects of medicinal cannabis?

Like other medicines, patients treated with medicinal cannabis can experience undesirable side effects. Below we list some of the common side effects for CBD-only and CBD:THC combination products.

CBD-only

The most commonly reported side effects include:

- appetite change
- mood change
- diarrhoea
- fatigue
- irritability
- nausea
- weight gain or loss.^{20,21}

Less common side effects include:

- dose-related liver damage
- behavioural changes
- sedation.²¹

CBD:THC combination

The most commonly reported side effects include:

- confusion
- dry mouth
- a profound sense of unease or dissatisfaction (dysphoria)
- extreme happiness (euphoria)
- fatigue
- headaches
- nausea and vomiting
- vertigo.²²

Less common side effects include:

- convulsions
- hallucinations
- paranoia
- uncontrollable vomiting (Hyperemesis syndrome).²²

Like other medicines, medicinal cannabis products have the potential to react with prescription and over-the-counter medications, and herbal products.²¹

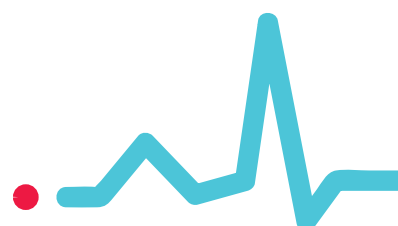
Will I experience withdrawal and dependence using medicinal cannabis products?

It is not uncommon for certain prescription drugs, even when taken as prescribed, to lead to physiological dependence. Withdrawal is the body's response to not having a substance after regular use.

There is some research that has highlighted that CBD products are not likely to cause physiological dependence and may possess anti-addictive properties. In contrast, high-THC products – due to its psychoactive properties – may pose an increased risk for withdrawal and dependence.^{23,24}

More research is needed to understand the dependence risks associated with different formulations of medicinal cannabis products.

Like other medicines, to minimise any risks associated with dependence and withdrawal, medicinal cannabis products must be supervised by a qualified medical professional and monitored appropriately.



What medicinal cannabis products are available in Australia?

In Australia, legally produced medicinal cannabis products fall into two categories – approved and unapproved. Both categories are only available through a medical practitioner.

Approved medicinal cannabis products are registered on the Australian Register of Therapeutic Goods (ARTG) and have been assessed for quality, safety and effectiveness by the TGA.

There are only two approved products currently available in Australia:

- nabiximols (brand name Sativex) which contains THC and CBD. Used to treat spasticity in people with MS
- cannabidiol (brand name Epidyolex) which is a CBD-only oil preparation. Used with other epilepsy drugs to treat severe and rare forms of epilepsy in children aged two years and over.

Unapproved medicinal cannabis products can be accessed by registered medical practitioners through the TGA's access pathways, outlined below.



Special Access Scheme (SAS)	For supplying unapproved therapeutic goods for a single patient. • SAS category A: for patients who are seriously ill and death is likely to occur • SAS category B: for all other patients who do not fit SAS-A definitions. This is the most common path for prescribing medicinal cannabis in Australia.
Authorised Prescriber Scheme (APS)	Medical practitioners are granted authority to prescribe unapproved therapeutic goods to multiple patients with a specific medical condition, such as paediatric epilepsy, multiple sclerosis, and palliative care.

A list of manufacturers and suppliers of medicinal cannabis products is available [here](#).

How do I access medicinal cannabis products?

If you're interested in medicinal cannabis products for an existing medical condition, the first step is to talk with your GP or specialist.

If your doctor believes medicinal cannabis treatment is clinically appropriate, they can apply online to the TGA and approval usually takes 24-48 hours.²⁵

Once approved, your doctor completes a prescription that can be filled and dispensed at an authorised pharmacy.

Some doctors are reluctant to prescribe medicinal cannabis for their patients. This may be because they feel uncertain about how to apply to access it, the supporting evidence and/or the different products available.²⁵

Each state and territory has different laws and regulations about accessing medicinal cannabis products,^{10,25} so your prescribing doctor should check your state or territory's health department requirements.²⁵

Access clinics are another option. These clinics are staffed by registered Australian doctors who specialise in treating patients with medicinal cannabis. Many of these clinics provide both in-clinic and telehealth services that can be accessed through their websites.

A list of cannabis access clinics around Australia is available [here](#).

You may also be able to access medicinal cannabis products through a clinical trial, if your condition is currently being studied and you meet the study inclusion criteria.

Information about current and upcoming clinical trials can be found on the Australian Clinical Trials [webpage](#).

It's important to note that one of the biggest barriers to accessing medicinal cannabis products is the cost.²⁶ There's currently no subsidy available for medicinal cannabis products under the Pharmaceutical Benefits Scheme (PBS).

The high price of medicinal cannabis products makes them out of reach for many people.

The *Australian Pain Management Association* reports patients paying \$300 - \$500 for initial appointments, and *Painaustralia* reports people with chronic pain pay around \$350 per month for their medicinal cannabis treatment.^{27,28}



How do people take medicinal cannabis products?

More than 100 different medicinal cannabis products are available in Australia.

They can be prepared and taken in a range of ways including vaporising, oils and liquid capsules, oro-mucosal sprays (under the tongue), or topically (applied to the skin).

Each delivery method has benefits and drawbacks – as shown in the table below.



Oral oils and liquid capsules	Most commonly prescribed method in Australia (approx. 80%). Slow onset (30-60 minutes); long duration (8-24 hours). ¹¹
Vaporising	No vaporisers are currently TGA approved. Very rapid onset (90 seconds); short duration (2-4 hours) – may be useful when immediate effects are required. ¹¹
Oro-mucosal sprays	Slow onset (90 minutes); long duration (8-24 hours). ¹¹
Topical	More research is required. THC appears poorly absorbed via skin; CBD appears to be better absorbed. The onset and duration of effects is unknown. ¹¹

Smoking medicinal cannabis products is not supported by the TGA. Smoking of any kind can damage the lungs and increase the risk of cancer, heart disease and other health conditions.¹¹

What's the difference between illegal and legal medicinal cannabis products?

Changes in legislation on cannabis use in different states and territories can be confusing when it comes to working out what's legal and what's not.

Medicinal cannabis was legalised in Australia in 2016 - but it's still a strictly controlled product, with the TGA responsible for regulating and approving medicinal products to ensure quality.

So, while medicinal cannabis products have been legalised as medicine, how you get them is controlled. It's illegal for people to order products online or import them for personal use.

The TGA warns of **the risks** of purchasing medicinal cannabis products on the internet or from overseas. These products can be contaminated, have undisclosed ingredients, and contain different doses of active ingredients than reported.²⁹

Each state and territory has its own policies on medicinal cannabis which determine how you can access medicinal cannabis products.

Where do I get information about accessing medicinal cannabis products in my state or territory?

You'll find links below to each state and territory's health department with relevant information and laws about accessing medicinal cannabis products.

- [ACT](#)
- [New South Wales](#)
- [Northern Territory](#)
- [Queensland](#)
- [South Australia](#)
- [Tasmania](#)
- [Victoria](#)
- [Western Australia](#).



Need more information?

Visit:

- [NPS MedicineWise Consumer Information](#)
- [TGA Information line](#) – call 1800 020 653
- [Lambert Initiative for Cannabinoid Therapeutics, University of Sydney](#)
- [Australian Centre for Clinical and Research Excellence](#)
- [Therapeutic Goods Administration \(TGA\)](#)

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