

Medicinal cannabis: What would you like to know?

There is a lot of interest in the use of cannabis as a medicine. You, or someone you know may be considering using medicinal cannabis.

- ▶ How and in what situations can it be used?
- ▶ What is it used for?
- ▶ Is medicinal cannabis legal and where can you access it?

These are just some of the questions Australians are asking. Often, the answers depend on which state or territory you live in.

NPS MedicineWise has developed a list of frequently asked questions about medicinal cannabis to help you find answers. For your benefit we have provided a list of state and territory resources at the end of these FAQs because each state/territory has slightly different laws and regulations.

What is medicinal cannabis?

Cannabis – a flowering plant in the Cannabaceae family and one of the world’s oldest cultivated plants – has been used by humans for multiple purposes over thousands of years.

Cannabis contains chemicals called phytocannabinoids (‘phyto’ is a Greek word meaning ‘of a plant’). Cannabinoids can also be found within the human body (endocannabinoids) and can be produced synthetically in a laboratory (synthetic cannabinoids).

Medicinal cannabis products are predominantly extracts from the cannabis plant – called ‘phyto-cannabinoids’ – used to treat an expanding list of medical conditions including epilepsy, multiple sclerosis, chronic non-cancer pain, nausea and vomiting due to chemotherapy, and palliative (end-of-life) care. Medicinal cannabis products include oils, capsules and sprays.

Synthetic cannabinoids are chemical compounds that have been produced in the laboratory to mimic the actions of phytocannabinoids. Some have been developed for medicinal use, although none are approved by the TGA. Other, less standardised synthetic cannabinoids can have more harmful side effects than phytocannabinoids, and when used have resulted in a number of deaths.

In Australia, medicinal cannabis is different to recreational cannabis (also known as marijuana) in that:

- ▶ medicinal cannabis products must comply with the Australian standards for producing pharmaceutical grade medicines
- ▶ it contains known quantities of the cannabinoids tetrahydrocannabinol (THC) and/or cannabidiol (CBD) whereas recreational cannabis usually contains unknown and high quantities of THC
- ▶ it is cultivated and manufactured legally
- ▶ it is intended to address a health condition or symptom.

For more details, see ‘How does medicinal cannabis work?’

Why is Australia treating medicinal cannabis as a medicine?

Medicinal cannabis may offer benefits, but it may also cause harm. Medicinal cannabis is a therapeutic good, which means it is regulated to ensure its safety for those Australians for whom it is prescribed.

Pharmaceutical quality medicinal cannabis that has been developed to treat an illness or reduce symptoms is required by law to meet stringent Australian quality and safety standards. This includes having a known dose of cannabinoids – the chemical components of cannabis – and not containing

any moulds, fungi, bacteria, pesticides, heavy metals, or other potentially harmful substances.

It is important to note that medicinal cannabis is not considered a 'first line' treatment for any health condition. Treatment with medicinal cannabis should only be considered by a prescribing doctor once all other standard, approved treatments have been unsuccessful.

How does medicinal cannabis work?

Cannabis contains chemicals called phytocannabinoids ('phyto' is a Greek word meaning 'of a plant'). There are more than 100 different types of phytocannabinoids which are commonly referred to simply as 'cannabinoids'. Two of the most common cannabinoids used in medicinal cannabis are:

- ▶ **THC** (delta 9-tetrahydrocannabinol) may be used to reduce symptoms of nausea, vomiting, pain and muscle spasticity, as well as to improve sleep and appetite. In some individuals THC may cause a 'high'*
- ▶ **CBD** (cannabidiol) does not cause a 'high'* and may reduce the unwanted adverse effects of THC. Research is continuing into the medicinal uses of CBD and THC combined, but it is thought to be useful in the management of seizures and pain and may also reduce anxiety.

* The 'high' effects of cannabis are often described as feeling relaxed, seeing colours more vividly, laughing spontaneously, feeling excitement, having an increased appetite among other effects. These experiences may not always be pleasant, and can lead to mild anxiety, depression or intense paranoia.

Cannabinoids act on receptors in the brain – and in other parts of the body – by mimicking naturally occurring cannabinoids (called 'endocannabinoids'). In the human body, the endocannabinoid system affects physical processes including appetite, sleep, memory, pain and inflammation.

What are the laws and regulations on medicinal cannabis?

The laws and regulations on medicinal cannabis operate at two levels: 1) national and 2) state/territory.

1) On 30 October 2016, the Australian law on medicinal cannabis was changed. Federal Parliament made amendments to the Narcotics Drugs Act 1967 to allow the cultivation and manufacture of cannabis for medical or research purposes.

An Australian government licencing and permit scheme that regulates the growing of cannabis plants and the production of medicinal cannabis products was introduced.

The scheduling* for medicinal cannabis now states that:

- ▶ medicinal cannabis products containing THC are classified as Schedule 8 (controlled, prescription-only medicines)
- ▶ medicinal cannabis products are classified as Schedule 4 (prescription only medicines) where;
 - a) CBD comprises 98% or more of the total cannabinoid content; and
 - b) any cannabinoids other than CBD must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content.

2) Each Australian state and territory has their own policies on medicinal cannabis and these determine how you can gain access to medicinal cannabis products. For more details, see '[Where do I go for more information?](#)'

*Scheduling is a national classification system that comes under legislation called the Poisons Standard. Scheduling controls how medicines and poisons are made available to the public.

For more information on scheduling visit www.tga.gov.au/scheduling-basics

For a list of state and territory contacts [visit the Therapeutic Goods Administration \(TGA\) website](#)

How does the research guide use of medicinal cannabis in Australia?

Over the past few years, a growing number of Australians have expressed interest in the use of cannabis for medicinal purposes. Because cannabis was classified as a prohibited substance for many decades, there have been a limited number of well-designed clinical studies on medicinal cannabis. For this reason, it can be difficult for doctors to find quality evidence to support their prescribing decisions.

The Australian Government Department of Health, in conjunction with state and territory health departments, has developed a series of clinical guidance documents for prescribers. So far, guidance documents have been developed to support prescribers of medicinal cannabis products for treating;

- ▶ nausea and vomiting due to chemotherapy
- ▶ epilepsy in children and young adults
- ▶ chronic non-cancer pain
- ▶ multiple sclerosis (MS)
- ▶ palliative (end-of-life) care

For summaries of evidence for the use of medicinal cannabis in each of the above conditions, download [Guidance for the use of medicinal cannabis in Australia: Patient information](#) from the TGA website.

What are some of the conditions where medicinal cannabis has been approved?

In Australia, the TGA has approved applications for the use of medicinal cannabis in conditions including, but not limited to:

- ▶ nausea and vomiting due to chemotherapy
- ▶ epilepsy in children
- ▶ palliative care
- ▶ cancer pain
- ▶ neuropathic pain
- ▶ spasticity from neurological conditions (such as multiple sclerosis)
- ▶ anorexia and wasting associated with chronic illness (such as cancer).

Find out more about the conditions where medicinal cannabis may be effective by visiting the [TGA website](#).

Who can prescribe medicinal cannabis?

Medicinal cannabis is subject to laws and regulations in Australia. Because medicinal cannabis is not considered as a 'first line' treatment for any condition, it should only be considered by a prescribing doctor if standard approved treatments have not worked effectively.

Read more: '[What are some of the conditions where medicinal cannabis has been approved?](#)'

If your doctor has been through the process of reading the evidence, making an assessment and reaching a conclusion that medicinal cannabis may be effective to manage your condition, they will need to:

- 1) contact the [Office of Drug Control](#) for a list of manufacturers and suppliers by visiting their website or calling 02 6232 8433
- 2) select the most appropriate product for you
- 3) apply for approval to prescribe the product from your local state or territory health department and the Australian government regulatory authority.

The application for approval is usually only made if you have tried other medicines without success and you are eligible to receive medicinal cannabis products for your condition, or if you are terminally ill with a short life expectancy.

As with prescribing any other medicine, the ultimate decision to prescribe (and in this case, the decision to apply for approval with the regulatory authority) lies with the prescribing doctor.

Of course, you will need to consult with the prescribing doctor and be kept informed during each step of this process. And, it is your decision to take medicinal cannabis if it has been prescribed for you.

Which medicinal cannabis products are approved for use in Australia?

Only one cannabis medicine, nabiximols (Sativex), is approved for use in Australia. Sativex contains equal amounts of tetrahydrocannabinol (THC) and cannabidiol (CBD) and is used for the treatment of muscle spasticity caused by multiple sclerosis (MS).

Sativex is a mouth spray that is indicated for muscle spasticity in people with MS.

Although Sativex is approved for use in eligible patients who have not responded to other treatments, it is not listed on the Pharmaceutical Benefits Scheme (PBS). This means that patients who are eligible to receive Sativex for their condition must pay the full cost themselves.

What about unapproved medicinal cannabis products?

Other medicinal cannabis products are available in Australia, but none of these have undergone assessment to be approved by the TGA. These are called 'unapproved medicines'.

Some doctors may apply for special access to an unapproved medicinal cannabis product if they follow national and state/territory approval processes. The application process is usually only made in certain circumstances; if the patient has tried other medicines without success and is eligible to receive medicinal cannabis for their condition, or if the patient is terminally ill with a short life expectancy.

For more information, read ['What are some of the conditions where medicinal cannabis has been approved?'](#)

Medicinal cannabis products must be obtained from approved manufacturers/suppliers to ensure their quality and purity, and to ensure they don't contain harmful substances.

The Office of Drug Control has a [list of manufacturers and suppliers of medicinal cannabis](#) on their website.

How do I take medicinal cannabis?

Medicinal cannabis is not considered to be a 'first line' treatment for any health condition. It should only be considered as a treatment if standard approved treatments have not worked effectively.

Before starting any medicine, seek advice from your doctor or pharmacist about how much to take, how to take it and what side effects you need to be aware of.

If you have been prescribed medicinal cannabis, always take the dose (amount) as directed.

Medicinal cannabis products can be taken in several ways:

► **Spray.** When sprayed into the mouth or under the tongue, medicinal cannabis can start to take effect between 10 minutes and 90 minutes, and effects are usually strongest after 2-4 hours. Using a spray may make it easier to get the right dose (amount) of cannabis medicine.

The only medicinal cannabis product registered for use in Australia by the TGA is an oral (mouth) spray called Sativex. This product is approved for use in people with multiple sclerosis (MS) who have tried other standard therapies without success.

► **Swallowing.** When swallowed as oils, liquid capsules or tablets, medicinal cannabis effects usually start after 30-90 minutes and are strongest after 2-4 hours. The effects may last 24 hours.



Swallowing cannabis medicine is best for longer term relief.

As it takes longer to feel the effects when swallowing a cannabis medicine, it is important to wait at least 3 hours before taking another dose to avoid accidental overdose.

- ▶ **Vaporising.** Vaporising heats the cannabis without burning it and releases the cannabinoids and other chemicals in the form of a vapour which is then inhaled. The effects can start after 90 seconds and are usually strongest after 15–30 minutes. Vaporising is best for fast-acting, short-term relief.

A variety of vaporising technologies are on the market, the majority of which are not indicated for therapeutic use. If vaporised cannabis is to be used it is recommended that those which have been studied in a research setting and found to be safe and feasible are chosen for use.

Check the TGA website for information on accessing unapproved therapeutic goods, including vaporising devices, through schemes such as the Personal Import Scheme and the Special Access Scheme (SAS).

What are the side effects of medicinal cannabis?

The known side effects from medicinal cannabis treatment include, but are not limited to; fatigue and sedation, dizziness, confusion, nausea and vomiting, fever, decreased or increased appetite, dry mouth, and diarrhoea. Products high in tetrahydrocannabinol (THC) has been associated with feeling 'high' or feeling dissatisfied, depression, confusion, hallucinations, paranoid delusions, psychosis, and cognitive distortion (having thoughts that are not true).

Medicinal cannabis side effects are commonly dose-dependent, so it's important to follow the dosing recommendations.

Medicinal cannabis should only used under medical advice because it may interact with other medicines or cause side effects.

What if I experience side effects from a cannabis medicine?

If you have experienced a medicine-related side effect or adverse event, you must contact your doctor and, where serious, seek medical advice.

If you have experienced a serious cannabis-related adverse event, your doctor is required to [report the adverse event to the TGA](#) within 15 calendar days.

If you have concerns about your medicines arising from an overdose or suspected poisoning, call the **Poisons Information Centre** 24 hours a day on **13 11 26**. For emergencies call **000**.

In addition, you can report medicine-related side effects through the NPS Adverse Medicine Events (AME) line by calling **1300 134 237** from anywhere in Australia (Monday to Friday 9am to 5pm AEST excluding public holidays). Visit the [NPS MedicineWise website](#) for more information about reporting adverse events.

Adverse events can also be reported online to the TGA via their [Adverse Events reporting page](#).

Can I smoke medicinal cannabis?

No. Smoking increases the risk of cancer, stroke, heart disease and other serious health conditions. In addition, smoking medicinal cannabis makes it difficult to be sure you are getting the right dose of medicine. Smoking of cannabis products is not recommended.

When should medicinal cannabis not be used?

Medicinal cannabis is not appropriate for:

- ▶ people with an active or previous psychotic disorder, or active mood or anxiety disorder
- ▶ women who are pregnant, planning to become pregnant or breastfeeding
- ▶ people with unstable heart disease.

There is no information available on the most effective or safe dose (amount) of medicinal cannabis for various conditions. For this reason, starting doses should be low and increased slowly over time.

If your doctor prescribes medicinal cannabis for you, note that:

- ▶ Like all medicines, medicinal cannabis may have side effects. Find out '[What are the side effects of medicinal cannabis](#)'.
- ▶ You **should not** drive or operate machinery while taking medicinal cannabis. Measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine, blood and saliva many days after the last dose. Drug-driving is dangerous. It is also a criminal offence. You should discuss the implications for safe and legal driving with your doctor.
- ▶ Depending on the laws in your state or territory, driving while using medicinal cannabis could be illegal. Check with your [state/territory health department](#).
- ▶ Some workplaces may have a 'drug-free policy' and enforce regular or random drug screening. If you have been prescribed medicinal cannabis, it is important to investigate your workplace policy before commencing treatment. Speak to your prescribing doctor who may wish to refer the matter to an occupational health specialist.

Do the new laws mean I may legally grow and use cannabis?

No. The changes to the Narcotics Drugs Act 1967 to allow the controlled cultivation of cannabis for medicinal or scientific purposes under a national licencing scheme came into operation on 30 October 2016.

However, this law does not apply to growing or using cannabis for recreational or non-medical purposes. The use or cultivation of cannabis outside of regulated medicinal purposes remains illegal.

People cannot legally grow their own cannabis for medicinal use even if it has been prescribed to them by an authorised doctor.

Each state and territory have their own law on possession of cannabis for recreational use. To find out more, search the government or police website for your state or territory.

Read more: '[What are the risks of buying medicinal cannabis online?](#)'

How do I access medicinal cannabis?

If you have a health condition – such as chronic pain, epilepsy, nausea and vomiting due to chemotherapy – where standard approved treatments have not worked for you, or they produce unacceptable side effects, your doctor may consider prescribing medicinal cannabis for you through a process called the Special Access Scheme (SAS) or via the Authorised Prescriber (AP) scheme.

Under SAS your doctor must discuss the options with you and apply for approval from state/territory authorities. Currently agreed approval timelines for all states and territories are estimated to be 2 days, where the online SAS system has been used and all required information has been provided.

As part of the process, your doctor must say which studies show why medicinal cannabis may work for you. In addition, medicinal cannabis must comply to Australian standards (defined in the [Therapeutic Goods Order 93](#)) and be lawfully made in Australia or imported from overseas.

Depending which state or territory you reside in, your pharmacist/pharmacy may need to be approved in order for them to supply, store and dispense medicinal cannabis.



If you require medicinal cannabis for palliative (end-of-life) care, your doctor need only notify the authorities – there is no need to apply for approval. This is known as a ‘compassionate’ use of the Special Access Scheme (SAS). For more information about the SAS and AP schemes visit the TGA website.

What are the risks of buying medicinal cannabis online?

Medicines that are not regulated by the TGA, and can be ordered from overseas, carry a number of risks.

- ▶ They may be counterfeit and contain no active ingredients.
- ▶ They may contain unknown amounts of the active ingredient and either be too weak to help you, or strong enough to harm you.
- ▶ They may be contaminated or adulterated with toxic substances.
- ▶ They may contain undisclosed or dangerous ingredients.

Australia has a very good system for maintaining the safety and quality of medicines that are sold here.

Medicinal cannabis is being regulated as a medicine in Australia to ensure the safety of the people for whom it is prescribed.

Even in the presence of an authorised prescription, it is illegal for an individual to personally order medicinal cannabis products online, or to import medicinal cannabis for personal use. The licence to import will only be issued by the Office of Drug Control to doctors or pharmacists.

Where do I go for more information?

- ▶ [Australian Centre for Cannabinoid Clinical and Research Excellence](#)
- ▶ [Centre for Medicinal Cannabis Research and Innovation](#)
- ▶ [NPS MedicineWise consumer information](#)
- ▶ [NPS Medicines Line](#) Call 1300 633 424 (Monday to Friday 9am to 5pm AEST)
- ▶ [NSW Cannabis Medicines Advisory Service](#) for NSW registered health professionals
Call 02 4923 6200 or email: HNELHD-CMAS@health.nsw.gov.au
- ▶ [TGA Information line](#) Call 1800 020 653
- ▶ [healthdirect](#)
- ▶ [Lambert Initiative for Cannabinoid Therapeutics, Sydney University](#)
- ▶ [MS Australia](#)

Australian government regulatory authorities:

- ▶ [Therapeutic Goods Administration \(TGA\)](#)
- ▶ [Office of Drug Control](#)

State and territory health departments:

[ACT](#)

[Northern Territory](#)

[NSW](#)

[Queensland](#)

[South Australia](#)

[Tasmania](#)

[Victoria](#)

[Western Australia](#)

Our information sources

ACT Health, Alcohol and Drug Foundation, Australian Centre for Cannabinoid Clinical and Research Excellence, Centre for Medicinal Cannabis Research and Innovation, Department of Health, Department of Health and Human Services Tasmania, healthdirect, Health Victoria, Lambert Initiative for Cannabinoid Therapeutics, NSW Cannabis Medicines Advisory Service, NSW Health, NT Health, Office of Drug Control, Queensland Health, Royal Australian College of General Practitioners, SA Health, Therapeutic Goods Administration (TGA), WA Health.