

In November 2016, medicinal cannabis was reclassified, making it a legal treatment option in Australia for healthcare practitioners to prescribe via the TGA Special Access Scheme (SAS) and Authorised Prescriber (AP) pathways.

Medicinal Cannabis is a pharmaceutical grade cannabinoid-based medicine prescribed by a registered healthcare professional for medical purposes, usually where standard treatment options have failed.

## The Endocannabinoid System (ECS)

Medicinal cannabis interacts with the human endocannabinoid system, a neurotransmitter system contained throughout the human body. There are natural endocannabinoid receptors (CB1 and CB2) found in the nervous and immune systems and elsewhere. There are natural ligands to these receptors (anandamide and 2-AG). The ECS is known to have a wide range of effects and plays a role in regulating a range of functions including appetite, bone health, fertility, immune function, inflammation, mood, memory, pain sensation, skin health, sleep, and stress response.

Cannabinoids can be produced in three ways, endocannabinoids (produced in the human body, phytocannabinoids (produced in plants), and synthetic cannabinoids (laboratory-made).

*Endocannabinoids and their receptors are found throughout the body: in the brain, organs, connective tissue, glands and immune cells. In each tissue, the cannabinoid system performs different tasks, but the goal is always the same: homeostasis, the maintenance of a stable internal environment despite fluctuations in the external environment. [5] Dr Dustin Sulak*

## Cannabinoids

The cannabis plant is known to contain more than 140 cannabinoids. The most researched are tetrahydrocannabinol (THC) and cannabidiol (CBD).

- THC is the main psychoactive cannabinoid in cannabis and has effects on feelings, mood and appetite
- CBD is a major suppressor of psychoactive effects, and has anti-anxiety, anti-inflammatory and anti-seizure effects

The ratio of THC to CBD helps determine the therapeutic effects of medicinal cannabis. Other cannabinoids of interest include CBDA, CBDV, THCA, THCV, CBG, CBN, and CBC, which are the focus of studies for medical purposes.

## Prescribing Medicinal Cannabis

There are four pathways through which prescribers can access medicines not yet approved for listing on the Australian Register of Therapeutic Goods (ARTG), also referred to as 'unapproved' medicines. To access 'unapproved' medicinal cannabis products for patients who have been assessed as clinically suitable the four pathways are as follows:

1. Authorised Prescriber - Established History of Use pathway
2. Authorised Prescriber - Standard pathway
3. SAS Category A notification pathway
4. SAS Category B application pathway

Prescribers will need to submit an application to the TGA to become an Authorised Prescriber for a particular cohort of patients within their practice OR submit a SAS application for a particular category of 'unapproved' medicinal cannabis for each patient before issuing the prescription.

When prescribing for patients under the age of 18 via the SAS Category B pathway, medical practitioners prescribing 'unapproved' medicinal cannabis products containing THC (cannabis category 2,3,4,5) are required to provide evidence of support from a paediatric specialist or relevant medical specialist supporting the use of the product for the patient's medical condition. Nurse practitioners may prescribe CBD-only medicines (Cannabis Category 1) for paediatric patients with a letter of support from a medical practitioner or proof that their scope of practice encompasses child and adolescent health.

Medicinal cannabis legislation and access differ slightly from state to state. Check the local state or territory regulations here:

**ACT:** <https://www.health.act.gov.au/health-professionals/pharmaceutical-services/controlled-medicines/medicinal-cannabis>

**NSW:** <https://www.medicinalcannabis.nsw.gov.au/health-professionals>

**NT:** <https://health.nt.gov.au/professionals/medicines-and-poisons-control2/therapeutic-medicines-containing-cannabinoids-medicinal-cannabis>

**QLD:** <https://www.health.qld.gov.au/public-health/topics/medicinal-cannabis/prescribing>

**SA:**  
<https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/conditions/medicines/medicinal+cannabis/medicinal+cannabis+patient+access+in+south+australia>

**TAS:** <https://www.health.tas.gov.au/health-topics/medicines-and-poisons-regulation/medicinal-cannabis/information-about-medicinal-cannabis-prescribers-tasmania>

**VIC:** <https://www.health.vic.gov.au/drugs-and-poisons/medicinal-cannabis-information-for-health-professionals>

**WA:** [https://www.health.wa.gov.au/articles/a\\_e/cannabis-based-products](https://www.health.wa.gov.au/articles/a_e/cannabis-based-products)

The TGA also provides information in the [Medicinal Cannabis Hub](#).

## Patient Eligibility

Patients are eligible for medicinal cannabis if they have a diagnosed chronic condition which has not responded to conventional treatments.

## Clinical Considerations

To ensure optimal patient outcomes, safety considerations should be assessed at each step of a patient's journey. Prior to prescribing, a patient should be screened for prior cannabis experience, symptom severity, current therapies, contraindications, and potential drug interactions. If the benefit is deemed to outweigh the risks, then

1. proceed by choosing the best suited route of administration,
2. the best suited ratio of CBD:THC,
3. start with a low dose, and slow titration method, keeping all concomitant medication doses stable during this time.
4. upon initiation with medicinal cannabis, monitor the patient regularly for adverse event and drug interactions.

## Contraindications and Drug interactions

Contraindications for cannabis generally include unstable cardiac conditions, pregnancy, breastfeeding, and people with psychosis. HCPs should screen for recreational, prescription and over the counter (OTC) medications.

Generally, it is believed medicinal cannabis can be safely used concurrently with most medications. The main considerations involve compounded sedation or impairment from depressants and potential drug-drug interactions with drugs metabolised by the cytochrome P450 enzymes.

## Practical Applications in Product Selection, Dosing, Titration and Monitoring

### Product Selection Guidance

Each route of administration (oral, oral mucosal, inhalation) has unique pharmacological properties leading to differing onsets of action, duration and effects. The appropriate administration technique should be matched to the symptoms being controlled

Routes	Vaporisation	Oral	Oral mucosal
<b>Symptom</b>	Acute/episodic	Chronic	Chronic
<b>Appropriate patient population</b>	Recommended for patients requiring rapid onset of action (migraines, nausea, acute pain, appetite, initiation of sleep)	Recommended for most patients with chronic symptoms	Recommended for most patients with chronic symptoms
<b>Onset (minutes)</b>	5-10	60-180	15-45
<b>Duration (hours)</b>	2-4	6-8	6-8
<b>Product formats and uses</b>	Dried flower, vape cartridges  Vaporisation requires a vaporiser that heats the product and releases vapor for inhalation	Oils, capsules	Sprays, wafers  Oral mucosal formats are applied sublingually or buccally
<b>Benefits</b>	Rapid onset of action. Doses can be quickly titrated to desired effect.	Longer duration of action to provide relief for chronic symptoms	Intermediate onset and duration of action
<b>Risks</b>	Require dexterity to prepare and administer  Vaporisers can be expensive	Slower titration due to delayed onset, delayed peak of action and interindividual variability in dosing requirements	Limited availability of product format

## Treatment Algorithm

Symptom:

Type of symptom	Acute, Intermittent	Chronic, Persistent
Product format	Vaporise	Oral, Oral Mucosal

Product:

CBD:THC Ratio	CBD Dominant	Balanced	THC Dominant
	CBD100, 1:20	10:10	20:1
May be effective for	Epilepsy, inflammatory pain, anxiety, onset insomnia	Nociceptive pain, maintenance insomnia, agitation	PTSD related sleep disturbance, sleep with pain

## Special populations considerations

Cannabis naïve patients, paediatric, geriatric, frail: may only need 0.1-0.5 or initiation dose

- Cannabis experienced patients: dosing advice should consider tolerance and accumulation of THC in the body
- Paediatric patients: avoid THC
- Geriatric patients: consider comorbidities, drug-to-drug interactions and metabolism, risk of sedation, and fall risk.

## Dosing and Titration Guidance

For safe initiation and titration, a 'start low, go slow' dosage plan is recommended to achieve treatment goals with minimal side effects.

Slow dose titration enables the patient to build a tolerance to THC, reducing the risk of adverse effects and impairment.

The optimal therapeutic dose is the lowest dose that offers symptom control with minimal or no adverse effects.

Most patients respond to 50-100 mg/day of CBD and less than 40 mg/day of THC (ref: 2021 MacCallum C, Medical Cannabis: Quick Reference Practice Tools)

Example Medicinal Cannabis Oil Titration Guide:

Weeks 1-2: Daily Dose	AM dose	PM dose	3 <sup>rd</sup> dose	Dose/day (mL)
Day 1-2	0.5 mL	0.5 mL	X	1 mL
Day 3-4	0.75 mL	0.75 mL	X	1.5 mL
Day 5-6	1 mL	1 mL	X	2 mL
Day 7-8	1.25 mL	1.25 mL	X	2.5 mL
Day 9-10	1 mL	1 mL	1 mL	3 mL
Day 11-12	1.2 mL	1.2 mL	1.2 mL	3.6 mL
Day 13-14	1.4 mL	1.4 mL	1.4 mL	4.2 mL
Day 15 onwards	Continue up titrating the dose until therapeutic benefit is achieved or dose is not tolerated			

## Example Medicinal Cannabis Dried Bud Titration Guide:

1. Start with 1 inhalation
2. Wait 15-30 minutes
3. Increase by 1 inhalation
4. Repeat until symptoms improve

The final dose is the total consecutive inhalations required for symptom relief.

### Regular Monitoring

Weekly or fortnightly follow up visits should be arranged with patients after initiating treatment to assess measurable efficacy and tolerability and identify potential safety risks.

The following components should be addressed:

- Current treatment regimen (dose, route of administration, frequency, quantity)
- Efficacy and symptom control
- Assessment and management of adverse effects
- Potential drug interactions

Patient journals tracking dose and efficacy are highly recommended to assist in monitoring.

Patients should trial product for 1 to 3 months to determine efficacy in treatment of symptoms. If no benefit is seen after trial, consider a product with different THC:CBD ratio.

## References

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