

Spectrum Therapeutics™ medicinal cannabis products are not registered in Australia. Spectrum Therapeutics products are SCHEDULE 8 drugs NON-ARTG medications and should only be ordered upon receipt of prescription and either TGA SAS B approval or Authorised Prescriber documents.

Medicinal Cannabis Pharmacist Information

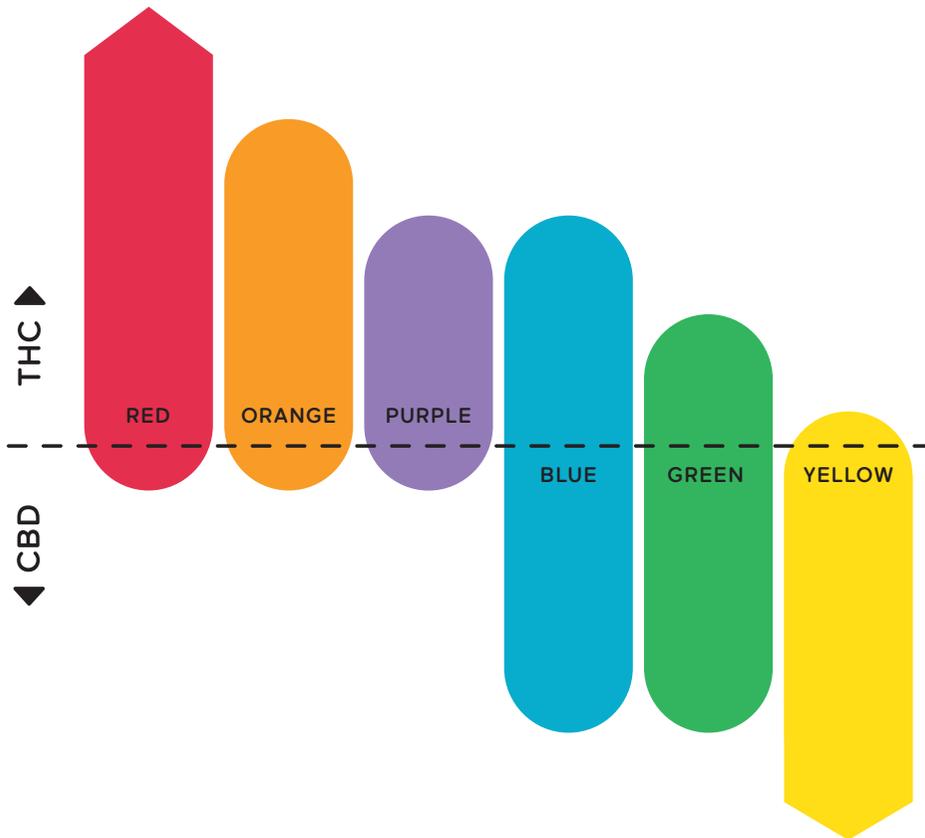




About Spectrum Therapeutics

Spectrum Therapeutics provides medicinal cannabis to patients in Australia and around the world. In addition to a consistent supply of lab-tested medicine, we keep you up to date with clear and accurate information.

We are driven by a strong focus on quality, evidence, safety, and education. As we invest in research, our goal is to deliver innovative medicines that raise the bar on therapy and outcomes for patients everywhere.



Your Guide to the Spectrum Therapeutics Framework™

The Spectrum Framework is a colour-coding system that helps healthcare professionals and patients communicate clearly about medicinal cannabis products.

Each colour represents a category of products based on THC and CBD content. Depending on the patient's clinical needs, a patient might be recommended a product containing THC, CBD, or a combination of both.

- **Red** represents products that are THC dominant with low levels of CBD.
- **Blue** represents products that have a more balanced ratio of THC and CBD.
- **Yellow** represents products that are CBD dominant with low levels of THC.

Dosing Information

Dosing for medicinal cannabis must be individualised to a patient's needs. A start low, go slow titration schedule is recommended.

As a general guide:

- THC doses exceeding 20–30 mg/day may increase the risk of adverse events or induce tolerance

(Reference: MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. *Eur J Intern Med* 2018;49:12–19)

- Maximum doses of CBD have not been established except in some therapeutic uses such as seizure disorders (2500 mg or 25–50 mg/kg)
- The majority of patients are dosed between 100–800 mg/day depending on the therapeutic use

(Reference: World Health Organization. Cannabidiol (CBD). Critical Review. Report. Expert Committee on Drug Dependence. Fortieth Meeting. Geneva, 4–7 June 2018)

- Spectrum Therapeutics oils and softgels are for oral consumption only

Once-daily dosing is recommended while the patient is establishing the most appropriate dose. Once a patient has reached an optimal dose, the doctor can consider switching to twice-daily dosing if they feel this is more suitable for the patient.

Spectrum Therapeutics Oil Dosing

<i>This dosing table serves as a guide. The dose may differ based on the prescribers recommendations.</i>		INCREASE ONLY IF NEEDED		
Spectrum Cannabis Oil Product Colour	Starting Dose Day 1	Day 2	Day 3	Day 4
Red THC 26.3 mg/mL CBD <1 mg/mL	0.1 mL	0.2 mL	0.3 mL	0.4 mL
Blue THC 10.0 mg/mL CBD 15.0 mg/mL	0.25 mL	0.5 mL	0.75 mL	1.0 mL
Yellow THC <1.0 mg/mL CBD 20.0 mg/mL	0.25 mL	0.5 mL	0.75 mL	1.0 mL

Your patient should find their optimal dose by starting with the oil formulation. Once your patient has achieved their optimal dose, your patient can switch to the softgels.

Spectrum Therapeutics Soft Gel Dosing

2.5 mg THC Capsules			10 mg THC* Capsules		
Red 2.5 mg THC <1mg CBD		Blue 2.5 mg THC 3.75mg CBD	Red 10 mg THC <1mg CBD		Blue 10 mg THC 15mg CBD
DAY	# SOFTGELS TAKEN TOGETHER	TOTAL THC	DAY	# SOFTGELS TAKEN TOGETHER	TOTAL THC
Increase dose only if needed, and only increase by 2.5 mg in a day.					
1	1	2.5 mg	1	1 (10 mg)	10 mg
2	2	5 mg	2	1 (10 mg) +1 (2.5 mg)	12.5 mg
3	3	7.5 mg	3	1 (10 mg) +2 (2.5 mg)	15 mg
4	4	10 mg	4	1 (10 mg) +3 (2.5 mg)	17.5 mg

Yellow 20 mg CBD <1mg THC

20 mg Yellow Softgels are meant for patients who have determined their optimal dose is 20 mg CBD or greater.

If you are new to CBD, you should start with cannabis oil to find your optimal dose.

*This guidance applies if the patient has already determined that the most effective dose is 10 mg THC or greater. If the patient intends to increase the dose, it is recommended that it be done by only 2.5 mg of THC. The patient should NOT increase their dose by 10 mg of THC.

Effects for different patients may vary, even with the same cannabis product. Individuals may experience different effects from one day to the next depending on delivery method and personal factors such as food consumption and sleep. Refer to dosing guidelines provided by your patient's doctor.

Dosing Interactions

Cannabis is metabolised via the hepatic cytochrome pathway and excreted via the biliary tract into feces, along with urinary excretion of acid metabolites.

Because the cytochrome P450 enzyme system is implicated in the metabolism of THC and CBD, there are likely to be significant pharmacokinetic interactions, particularly with drugs that are metabolised by, or either inhibit or induce cytochrome P450 (CYP450) enzymes.

The clinical significance is greater for medications that have a narrow therapeutic window such as warfarin.

THC also has the potential to inhibit CYP isozymes 3A4, 3A5, 2C9, and 2C19, while CBD also has the potential to inhibit CYP 2C19, 3A4, and 3A5. There is a possibility that the bioavailability of drugs that are metabolised by these isozymes may increase with concurrent medicinal cannabis consumption, e.g., anti-coagulants (warfarin, apixaban, rivaroxaban), amitryptiline, phenytoin, theophylline, granisetron, dacarbazine, and flutamide.

(Reference: Health Canada - Information for Healthcare Professionals, Oct 2018)

THC Drug-Drug Interaction

Based on in vitro and animal studies with cannabis, there is a potential for interaction with the medications metabolised by the P450 enzymes (2C9, 2C19, 3A4).

Those that can increase THC levels include:

- Antidepressants (e.g., fluoxetine, fluvoxamine)
- Proton pump inhibitors (e.g., omeprazole)
- Cimetidine
- Macrolides (e.g., clarithromycin, erythromycin)
- Antimycotics (e.g., itraconazole, fluconazole, ketoconazole, miconazole)
- Calcium antagonists (e.g., diltiazem, verapamil)
- HIV protease inhibitors (e.g., ritonavir)
- Amiodarone
- Isoniazid

Drugs that may decrease the availability of THC include:

- Rifampicin
- Antiepileptic medication (e.g., carbamazepine, phenobarbital, phenytoin, primidone)
- Rifabutin
- St. John's wort

CBD Drug-Drug Interaction

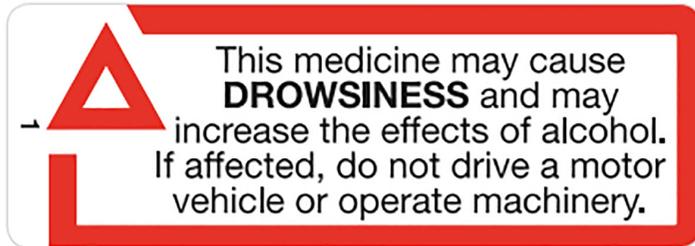
Similar to THC, CBD is also metabolised by CYP 450 pathway. As such, the bioavailability of CBD could potentially be increased by many of the same substances listed for THC, as well as bupropion, paroxetine, quinidine, clomethiazole, diallyl disulfide, diethyldithiocarbamate, and disulfiram.

(Reference: Health Canada - Information for Healthcare Professionals, Oct 2018)

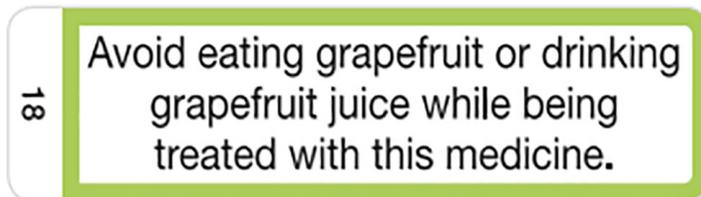
CBD may also cause an increase in the blood levels of the anticonvulsant clobazam. This combination should be used very cautiously and clinicians are strongly encouraged to seek expert medical advice.

Labeling

Label 1



Label 18



Storage and Record Keeping

- Store below 25 degrees C
- As a Schedule 8 medicine, this item needs to be stored securely in a safe and restricted access to only authorised staff such as a registered pharmacist
- Pharmacists are required to maintain records as per S8 requirements
- Do not need to refrigerate

Patient Counselling

1. It can take 30 minutes–2 hours or longer to feel the effects of oil or softgels.
2. It is important to allow at least 3 hours between administration of single oral dose to avoid possible over consumption. Effects can last up to 12 hours and as long as 24 hours.
3. These products should not be consumed by women who are pregnant or breastfeeding.
4. Always store cannabis products in their original packaging and keep out of reach of children and pets.
5. It is not recommended to add oil to baked goods or other food (e.g., yogurt) as dosing precision is lost.
6. Avoid consuming alcohol in combination with cannabis in any form.
7. Fatty meals may increase the effect that your patient experiences.
8. Do not drive or operate heavy machinery while using a THC-containing product.
9. Talk your patient through the CMI provided.

Practical Considerations

1. Most pharmacies in Australia can dispense medicinal cannabis*.
2. As per all S8 prescriptions, the pharmacist must verify the authenticity of the script, the identity of the person presenting the script and the details of the prescriber.
3. If the prescriber is from a different state, check with your local state health department before dispensing the prescription.
4. To order a medicinal cannabis prescription, distributors will require a copy of the TGA approval (SAS B or Authorised Prescriber approval).
5. Pharmacies cannot hold stock of medicinal cannabis products in anticipation of supply.
6. Dispensing and destruction of expired or returned medicinal cannabis stock is as per S8 regulations and requirements (e.g., entries must be recorded in the Drug of Dependence Book).

*There might be some differences in approvals of pharmacies which may restrict the supply of S8 medication or medicinal cannabis dispensing. Always check your pharmacy approval and state health regulations prior to dispensing.

How to Order

New Account Opening

Anspec Pty Ltd distributes Spectrum Therapeutics products on our behalf. An account with Anspec is required to facilitate supply. If a patient has presented to your pharmacy with a prescription for a Spectrum Therapeutics medicine and you do not currently have an account with Anspec, please complete the account opening form available on our website: spectrumtherapeutics.com/australia.

For Queensland pharmacies only—please supply PBS Medicare Approval to supply Pharmaceutical benefits Section 90 when opening an account.

Send your completed form and first order to: domesticorders@anspec.com.au.

A copy of the prescription is not required in line with Australian Privacy Principles.

Pharmacy Ordering Process

Medical practitioners can prescribe medicinal cannabis under the Special Access Scheme Category B (SAS B) or via the Authorised Prescriber (AP) pathway. The process to order a Spectrum Therapeutics product, regardless of the prescribing pathway, is outlined below:

NEW SCRIPT - Pharmacy needs to send:

1. TGA Approval in full or Authorised Prescriber document (all pages of the TGA approval or Authorised Prescriber document are required)
2. Doctor's Name
3. Patient Initials
4. Product Name
5. Quantity required

REPEAT SCRIPT - Pharmacy needs to send:

1. Patient Initials
2. Patient's Date of Birth
3. Doctor's Name
4. Product Name
5. Quantity Required

Contact Information

For order enquiries

Please contact Anspec for any account enquiries.
Anspec's contact details are:

Email: domesticorders@anspec.com.au

Phone: 02-8438 8681, 02-8438 8652 or 02-8438 8693

Fax: +61 2 8438 8699

For Medical Information

Our dedicated Spectrum Therapeutics Medical Information team is available to answer all your medicinal cannabis queries.

Email: medinfo.au@canopygrowth.com

Phone: 1800 223 842

Website: spectrumtherapeutics.com/australia

