

Spectrum Cannabis Softgels

Active ingredient(s): Extract of Cannabis species containing tetrahydrocannabinol (THC) and cannabidiol (CBD)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Spectrum Cannabis Softgels. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Spectrum Cannabis Softgels.

Where to find information in this leaflet:

- [1. Why am I using Spectrum Cannabis Softgels?](#)
- [2. What should I know before I use Spectrum Cannabis Softgels?](#)
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1. Why am I using Spectrum Cannabis Softgels?

Spectrum Cannabis Softgels contains the extract of Cannabis species in a softgel capsule containing tetrahydrocannabinol (THC) and cannabidiol (CBD). The ratio of THC to CBD varies in each formulation of Spectrum Cannabis Softgels i.e Yellow, Blue and Red Cannabis Softgels. THC and CBD are responsible for the different uses of medicinal cannabis and the unique properties of each individual cannabis variety.

Spectrum Cannabis Softgels may be used to:

- Provide pain relief
- Provide relief from nausea
- Improve sleep
- Improve anxiety
- Increase appetite
- Reduce inflammation
- Reduce spasticity
- Reduce occurrence of seizures

The therapeutic benefits of medicinal cannabis may vary depending on a patient's biology and the product selected. This list is not exhaustive. Your doctor will advise you on why medicinal cannabis may be used in your circumstances.

2. What should I know before I use Spectrum Cannabis Softgels?

Know where the product comes from. Always use medicinal cannabis from a trusted source to avoid contaminants and unregulated extracts.

Tell your doctor if you are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed.

Talk to your doctor about any:

- Allergies to medicines, food, dyes, or preservatives
- Medical conditions that you have or have had in the past (including any heart, liver, or kidney problems and drug dependence or alcohol dependence)

Tell your doctor about any medicines that you are taking, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Medicinal cannabis can interact with other medicines, particularly those that slow down the central nervous system, causing drowsiness and potentiating any side effects.

These medicines include other strong painkillers, medicines used to treat anxiety, depression, epilepsy, aids for sleep, muscle relaxants. This list is not exhaustive. Speak to your doctor or pharmacist if you are not sure if you are taking any of these medications.

Do not use Spectrum Cannabis Softgels if:

- You have a history of hypersensitivity to tetrahydrocannabinol (THC) or cannabidiol (CBD), or any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can use this medicine.

Go to Accident and Emergency at the nearest hospital or call 000 if you notice any of the following:

- Signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath

Spectrum Cannabis Softgels are not appropriate for patients who:

- Have severe and unstable heart disease (angina, peripheral vascular disease, cerebrovascular disease and arrhythmias) or risk factors for heart disease
- Are pregnant/breastfeeding
- Have unstable or untreated psychiatric conditions, including bipolar disorder, psychosis, or if actively suicidal

Check with your doctor if you:

- Are under 25 due to the potentially adverse effects on the developing brain
- Have severe liver or renal disease
- Have a history of drug dependence, including nicotine and heavy users of alcohol
- Have other medications, especially other sedatives such as opioids and benzodiazepines
- Are elderly or very young as these age groups of patients are likely to be more sensitive to the pharmacological effects of medicinal cannabis

During treatment, you may be at risk of developing certain side effects. It is important that you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

There is very limited evidence about how medicinal cannabis reacts with other approved medications. Most drug interactions are associated with drugs that slow down the nervous system, causing drowsiness such as sedatives, benzodiazepines, hypnotics with

Spectrum Cannabis Softgels.

Other drug interactions may include:

- Anti-depressants (*Fluoxetine, Fluvoxamine*)
- Anti-coagulants (*Warfarin, Apixaban, Rivaroxaban*)
- Antiretroviral drugs used in the treatment of HIV/AIDS
- Stomach acid inhibitors (*Omeprazole*)
- Certain antibiotic and antifungal medications
- Some heart medications (*Amiodarone, Diltiazem, Verapamil*)
- Some anti-epileptic medications (*Carbamazepine, Phenytoin, Clobazam*)
- St John's Wort.

One significant interaction is between high dose CBD with clobazam, wherein a dose reduction for clobazam may be required.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Spectrum Cannabis Softgels.

4. How do I use Spectrum Cannabis Softgels?

Dosing Table

2.5mg THC capsules			10mg THC capsules		
2.5mg THC <1mg CBD		2.5mg THC 3.75mg CBD		10mg THC <1mg CBD	10mg 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	2.5mg	1	1 (10 mg)	10mg
2	2	5mg	2	1 (10 mg) +1 (2.5 mg)	12.5mg
3	3	7.5mg	3	1 (10 mg) +2 (2.5 mg)	15mg
4	4	10mg	4	1 (10 mg) +3 (2.5 mg)	17.5mg

20mg CBD <1mg THC	
20mg Yellow Softgels are meant for patients who have determined their optimal dose is 20mg 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.

How much to take / use

If this is your first time consuming Spectrum Cannabis Softgels, follow the guidance listed in the Dosing Table or as instructed by your doctor. Wait one day before adjusting your dose or consuming more. If you find the starting dose ineffective after waiting a day, consume the Day 2 dose and wait another day to assess the effects before consuming more.

Continue in this manner until you reach your optimal dose*. Only increase by the recommended amount per day to avoid any uncomfortable effects.

Always follow the instructions of your doctor for dosing.

Follow the instructions provided and use Spectrum Cannabis Softgels until your doctor tells you to stop.

*The "optimal dose" is the dose achieved through gradually increasing the dose to the point that results in optimal benefit with minimal side effects. Once you have identified your optimal dose based on once-

daily dosing, you can adjust dose frequency based on the severity of symptoms throughout the day (e.g., take a morning and an evening dose).

If you forget to use Spectrum Cannabis Softgels

- Spectrum Cannabis Softgels should be used regularly at the same time each day.
- If you miss your dose at the usual time, talk to your doctor or pharmacist about the most appropriate time to take the missed dose.
- If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Do not take a double dose to make up for the dose you missed.

If you consume too many Spectrum Cannabis Softgels

If you experience symptoms of anxiety, nausea, dizziness, vomiting, or fainting, it is important that you don't panic.

You should focus on your breathing, stay hydrated, and find a safe place to relax.

The effects should wear off in 2-6 hours, depending on the method of consumption.

If health and safety become a concern, contact your doctor immediately.

Should you experience chest pain, persistent vomiting, or dizziness causing falls, you should go to Accident and Emergency at the nearest hospital or call 000 immediately.

If you think that you have taken too many Spectrum Cannabis Softgels, you may need urgent medical attention.

You should immediately:

- Phone the Poisons Information Centre (by calling 13 11 26), or
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Spectrum Cannabis Softgels?

Things you should do

Tell your doctor that you are taking Spectrum Cannabis Softgels:

- Before starting any new medicine
- If you become pregnant
- If you plan to have surgery, including dental surgery
- If you are about to have any blood tests

Talk to your doctor about the progress of your treatment.

If your condition is worsening while on Spectrum Cannabis Softgels, you should notify your doctor.

Things you should not do

- Do not stop taking your medicine suddenly. Always speak to your pharmacist or doctor before stopping any medicine.

Driving or using machines

You should not drive or operate machinery while being treated with Spectrum Cannabis Softgels. Measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine many days after the last dose. It may take up to five days for 80 to 90% of the dose to be excreted. Drug-driving is a

criminal offence, and you should discuss the implications for safe and legal driving with your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not consume Spectrum Cannabis Softgels and alcohol at the same time — their effects may magnify each other's, causing discomfort and inebriation.

Looking after your medicine

- Store below 25 degrees celcius it in a cool dry place away from moisture, heat or sunlight
- Spectrum Cannabis Softgels do not need to be refrigerated

Do not store your medicine:

- In the bathroom or near a sink, or
- In the car or on window sills

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines, including medicinal cannabis can have side effects. The extent of effects can vary with the type of medicinal cannabis product and between individuals.

See the information in the table below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side Effect	Most Common	Common	Rare
Drowsiness/fatigue	✓		
Dizziness	✓		
Dry mouth	✓		
Anxiety	✓		
Nausea	✓		
Cognitive effects	✓		
Euphoria		✓	
Blurred vision		✓	
Headache		✓	
Orthostatic hypotension			✓
Toxic psychosis/paranoia			✓
Depression			✓
Ataxia/dyscoordination			✓
Tachycardia (after titration)			✓
Cannabis hyperemesis			✓
Diarrhea			✓

Adapted from MacCallum and Russo, 2018

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine. Alternatively you can speak to your doctor or pharmacist to report the side effects.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product Details

This medicine is only available with a doctor's prescription together with the relevant federal and/or state approval.

What Spectrum Cannabis Softgels contain

Active ingredient (main ingredient)	Extract of Cannabis species containing tetrahydrocannabinol (THC) and cannabidiol (CBD)
Other ingredients (inactive ingredients)	Medium-chain triglyceride (MCT) oil, gelatin, glycerin, colour and purified water.

Do not take this medicine if you are allergic to any of these ingredients.

What do Spectrum Cannabis Softgels look like?

Spectrum Cannabis Yellow Softgels 20mg contains tetrahydrocannabinol (THC) <1mg and cannabidiol (CBD) 20mg; 30 softgels per bottle.

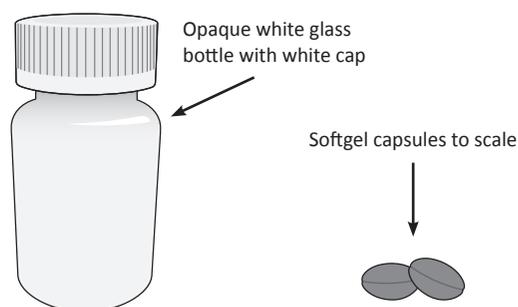
Spectrum Cannabis Blue Softgels 2.5mg contains tetrahydrocannabinol (THC) 2.5mg and cannabidiol (CBD) 3.75mg; 60 softgels per bottle.

Spectrum Cannabis Blue Softgels 10mg contains tetrahydrocannabinol (THC) 10mg and cannabidiol (CBD) 15mg; 30 softgels per bottle.

Spectrum Cannabis Red Softgels 2.5mg contains tetrahydrocannabinol (THC) 2.5mg and cannabidiol (CBD) <1mg; 60 softgels per bottle.

Spectrum Cannabis Red Softgels 10mg contains tetrahydrocannabinol (THC) 10mg and cannabidiol (CBD) <1mg; 30 softgels per bottle.

Each individual bottle contains Softgel capsules.



If you experience any difficulties with usage or have questions, please contact **Medical Information Hotline on 1800 223 842.**

Who supplies Spectrum Cannabis Softgels?

Spectrum Therapeutics Cannabis Softgels are supplied by Spectrum Therapeutics.

Spectrum Therapeutics™ medicinal cannabis products are not registered in Australia.

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