

# Spectrum Cannabis Oil

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

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## Consumer Medicine Information (CMI)

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This leaflet provides important information about using Spectrum Cannabis Oil. 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 Oil.

### **Where to find information in this leaflet:**

- [1. Why am I using Spectrum Cannabis Oil?](#)
- [2. What should I know before I use Spectrum Cannabis Oil?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Spectrum Cannabis Oil?](#)
- [5. What should I know while using Spectrum Cannabis Oil?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

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## 1. Why am I using Spectrum Cannabis Oil?

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

### **Spectrum Cannabis Oil 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.

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## 2. What should I know before I use Spectrum Cannabis Oil?

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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 Oil 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 Oil is 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.

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## 3. What if I am taking other medicines?

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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 any drugs that slow down the nervous system, causing drowsiness such as sedatives, benzodiazepines, hypnotics with Spectrum Cannabis Oil.

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.

**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 Oil.**

#### 4. How do I use Spectrum Cannabis Oil?

##### Dosing Table

This is a recommendation only. Your doctor will prescribe the most appropriate dose for you.		INCREASE ONLY IF NEEDED			
Spectrum Cannabis Oil Product	Starting Dose Day 1	Day 2	Day 3	Day 4	
<b>Red</b> THC 26.3 mg/mL CBD <1 mg/mL	0.1 mL	0.2 mL	0.3 mL	0.4 mL	
<b>Blue</b> THC 10.0 mg/mL CBD 15.0 mg/mL	0.25 mL	0.5 mL	0.75 mL	1.0 mL	
<b>Yellow</b> THC <1.0 mg/mL CBD 20.0 mg/mL	0.25 mL	0.5 mL	0.75 mL	1.0 mL	

##### How much to take / use

If this is your first time consuming Spectrum Cannabis Oil, follow the guidance listed in the Dosing Table and 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.

For simplified use and precise dosing, we have included a syringe along with your bottle. Please see below for directions for use.

When cleaning your syringe after each use, remove the plunger completely and clean with soap and water. It is important to ensure the syringe is completely dry before using it.

Follow the instructions provided and use Spectrum Cannabis Oil 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).

##### Directions For Use

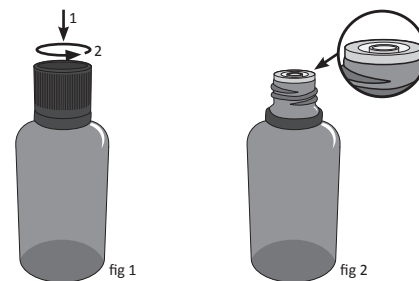
Spectrum Cannabis Oil Bottles are accompanied by a syringe required for oral ingestion.

Please follow these steps for correct dosing and administration.

When opening the bottle for the first time, in order to prevent the plastic bottle insert (PIBA) from getting stuck inside the cap, turn the cap in a clockwise motion - at which time you will hear a click which indicates that the press-in bottle adapter (PIBA) was inserted into the bottle. Following this, you may then proceed to open the cap. Please note, the cap is child-proof. Do not use if the tamper evident seal around the neck has been broken.

##### How to use Spectrum Cannabis Oil

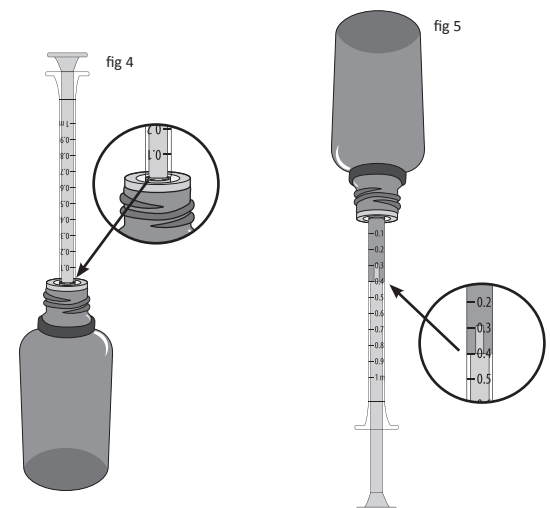
**Step One:** Open the bottle by turning the black cap anti-clockwise. (fig 1). Once removing the black cap, the bottle will contain the plastic bottle adapter as pictured (fig 2).



**Step Two:** Remove the cap from the syringe as shown (fig 3).



**Step Three:** Insert the syringe into the centre of the PIBA (fig 4). The syringe has been designed to fit firmly into the centre as pictured (fig 4).



**Step Four:** Once the syringe has been firmly secured into the stopper, turn the bottle upside down and draw the dose in accordance with the marked dosage (fig 5).

If you experience any difficulties with usage, please contact our Medical Information Hotline on 1800 223 842.

### **If you forget to use Spectrum Cannabis Oil**

- Spectrum Cannabis Oil 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 use too much Spectrum Cannabis Oil**

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 used too much Spectrum Cannabis Oil, 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.**

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## **5. What should I know while using Spectrum Cannabis Oil?**

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### **Things you should do**

#### **Tell your doctor that you are taking Spectrum Cannabis Oil:**

- 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 Oil, you should notify your doctor.

### **Things you should not do**

- Do not vaporise Spectrum Cannabis Oil. The oil is strictly for oral consumption.
- 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 Oil.** 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 Oil 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 Oil does 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.

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## **6. Are there any side effects?**

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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](http://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.**

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## **7. Product Details**

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

### **What Spectrum Cannabis Oil contains**

<b>Active ingredient (main ingredient)</b>	Extract of Cannabis species containing tetrahydrocannabinol (THC) and cannabidiol (CBD)
<b>Other ingredients (inactive ingredients)</b>	Medium-chain triglyceride (MCT) oil

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

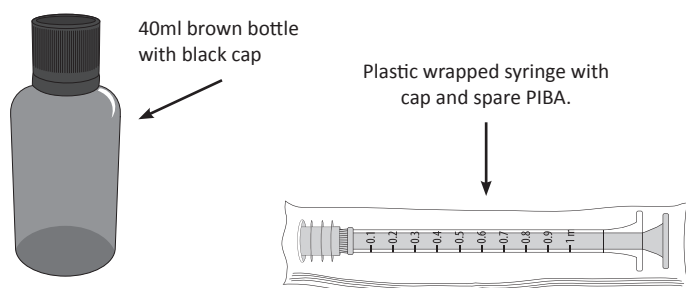
### **What does Spectrum Cannabis Oil look like?**

**Spectrum Cannabis Yellow Oil:** extract of Cannabis species containing tetrahydrocannabinol (THC) <1mg/ml and cannabidiol (CBD) 20mg/ml; 40ml bottle

**Spectrum Cannabis Blue Oil:** extract of Cannabis species containing tetrahydrocannabinol (THC 10mg/ml) and cannabidiol (CBD 15mg/ml); 40ml bottle

**Spectrum Red Oil:** extract of Cannabis species containing tetrahydrocannabinol (THC 26.3mg/ml) and cannabidiol (CBD <1mg/ml); 40ml bottle

Each individual bottle comes with a marked plastic syringe with cap.



### **Who supplies Spectrum Cannabis Oil?**

Spectrum Therapeutics Cannabis Oil is supplied by Spectrum Therapeutics.

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

Spectrum Therapeutics Pty Ltd. ABN 50 623 556 258. Suite 3, Building 26, 270 Ferntree Gully Road, Notting Hill VIC 3168.