



Medibis Cannabis Oil

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

Consumer Medicine Information (CMI)

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

1. Why am I using Medibis Cannabis Oil?

Medibis 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 Medibis Cannabis Oil (i.e. Highfields T20, and Eumundi E 10 Cannabis Oil). THC and CBD are responsible for the different uses of medicinal cannabis and the unique properties of each individual cannabis variety.

Medibis 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.

2. What should I know before I use Medibis Cannabis Oil?

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 Medibis 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.

Medibis 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.

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

4. How do I use Medibis Cannabis Oil?

How much to take / use

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 Medibis 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

Medibis Cannabis Oil Bottles are accompanied by a 1 ml syringe required for oral ingestion. Please follow these steps for correct dosing and administration.

Please note, the cap is child-proof. Do not use if the tamper evident seal around the neck has been broken.

How to use Medibis Cannabis Oil

1. Remove the child-resistant cap on the bottle by pushing the cap down whilst turning the cap anti-clockwise.



2. Ensure the bottle adaptor is firmly onto the neck of the bottle, making sure it is fully inserted. The adaptor could come off and cause choking if it is not fully inserted.



3. Insert the tip of oral syringe fully into the bottle adaptor, and with the oral syringe in place, turn the bottle upside down.



4. Slowly pull back the plunger of the syringe, so the volume of solution needed is drawn into the syringe. Line up the end of the plunger with the volume marking required, as shown opposite. If there is an air bubble in the syringe, push the liquid back into the bottle whilst keeping the bottle upside down, and repeat Step 5 until the bubble has gone.



5. Turn the bottle the right side up, and carefully remove the oral syringe from the adaptor.



- Place the tip of the oral syringe inside the cheek, and gently push the plunger to release the medicine. Do not push the plunger forcefully or direct the medicine to the back of the mouth or throat.



- Screw the child resistant cap back on the bottle tightly, by turning the cap clockwise – you do not need to remove the bottle adaptor, as the cap will fit over it.



- Screw the child resistant cap back on the bottle tightly, by turning the cap clockwise – you do not need to remove the bottle adaptor, as the cap will fit over it.
- Remove the plunger from the barrel of the syringe, and rinse both parts under tap water. Do not place the oral syringe in a dishwasher. Shake off any water from both parts and allow them to dry in the air until the next use. Make sure the oral syringe is completely dry before the next use, or it could make the solution appear cloudy if water gets in the bottle. If the solution in the bottle has turned cloudy, this doesn't change how well it works. Continue to use the medicine as normal.

If you forget to use Medibis Cannabis Oil

- Medibis 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 Medibis 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 Medibis 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.

5. What should I know while using Medibis Cannabis Oil?

Things you should do

Tell your doctor that you are taking Medibis 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 Medibis Cannabis Oil, you should notify your doctor.

Things you should not do

- Do not vaporise Medibis 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 Medibis 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 Medibis 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 Celsius in a cool dry place away from moisture, heat, or sunlight
- Medibis 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 windowsills

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	Most Common
Drowsiness/ fatigue	most common
Dizziness	most common
Dry Mouth	most common
Anxiety	most common
Nausea	most common
Cognitive effects	most common
Euphoria	common
Blurred vision	common
Headache	common
Orthostatic hypotension	rare
Toxic psychosis/ paranoia	rare
Depression	rare
Ataxial/ discoordination	rare

Tachycardia (after titration)	rare
Cannabis hyperemesis	rare
Diarrhea	rare

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 effect 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 approvals.

What Medibis Cannabis Oil contains

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

Other ingredients (inactive ingredients): Medium-chain triglyceride (MCT) oil.

What does Medibis Cannabis Oil look like?

Medibis Cannabis Oil: Highfields T20 extract of cannabis species containing tetrahydrocannabinol (THC) 20mg/ml & cannabidiol (CBD) < 1mg/ml. 30ml bottle.

Medibis Cannabis Oil: Eumundi E10 extract of cannabis species containing tetrahydrocannabinol (THC) 10mg/ml & cannabidiol (CBD) 10mg/ml. 30ml bottle.

Who supplies Medibis Cannabis Oil?

Medibis Cannabis Oil is supplied by Blue Mountain Global Pty Ltd T/As Medibis Pty Ltd.

Medibis medicinal cannabis products are not registered in Australia.
Medicine ABN 42 626 863 410. PO Box 573, Toowoomba, Qld, 4350.

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