

Patient information sheet

MediCabilis™ 5% CBD ECs315- *Cannabis sativa* L. oil extract

Providing –50mg CBD/mL. Available as 25 mL and 50 mL.



1. What is in the information sheet?

This information sheet answers some common questions about MediCabilis™ 5% CBD ECs315. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this information sheet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using MediCabilis™ 5% CBD ECs315 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this information sheet.

You may need to read it again.

2. What MediCabilis™ 5% CBD ECs315 is used for

Your doctor will prescribe MediCabilis™ 5% CBD ECs315 based on your individual health needs. MediCabilis™ 5% CBD ECs315 is a high CBD containing cannabis extract. Cannabis extracts may be prescribed to help manage a range of symptoms associated with a number of conditions including:

- Chemotherapy-Induced nausea and vomiting (CINV)
- Management of epileptic seizures and conditions
- Inflammatory bowel disease
- Inflammation related conditions
- Anxiety
- Multiple sclerosis (MS)
- Pain conditions included neuropathic pain, fibromyalgia, rheumatoid arthritis, and mixed chronic pain

Your doctor may also prescribe MediCabilis™ 5% CBD ECs315 for another purpose.

Ask your doctor if you have any questions about why MediCabilis™ 5% CBD ECs315 has been prescribed for you.

This medicine is only available with a doctor's prescription. MediCabilis™ 5% CBD ECs315 is not listed or registered with the TGA. Access is via clinical trial use, an authorised prescriber or through the TGA special access scheme.

3. Before you take MediCabilis™ 5% CBD ECs315

Do not use MediCabilis™ 5% CBD ECs315 if:

- You are allergic or hypersensitive to Cannabis extracts or any of the other ingredients listed in section 8.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- You or anyone directly related to you has any mental health problems such as schizophrenia, psychosis or any other significant psychiatric disorder.
- You are breast feeding. Do not use during pregnancy, unless advised to by your doctor.

Do not use this medicine after the expiry date printed on the pack, or if the packaging is showing signs of tampering.

Do not use this medicine if any of the above applies to you.

Talk to your doctor if you are concerned about starting this medicine.

Tell your doctor if:

- You are pregnant or plan to become pregnant.
- You are under 18 years of age.
- You have liver or kidney problems.
- You have a serious heart problem such as angina, a previous heart attack, poorly controlled high blood pressure or a problem with your heart rate or heartbeat.
- You are elderly, especially if you have problems doing everyday activities such as making hot food and drinks.
- You have previously taken any drug or substance recreationally.

If you have not told your doctor about any of the above, tell them before you start using MediCabilis™ 5% CBD ECs315.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking MediCabilis™ 5% CBD ECs315.

Some medicines may interfere with MediCabilis™ 5% CBD ECs315.

If any of the above apply to you (or you are not sure), talk to your doctor before using MediCabilis™ 5% CBD ECs315.

If you start seeing a different doctor or going to hospital, let them know all the medicines you are using.

4. How to take MediCabilis™ 5% CBD ECs315

Method of administration:

The bottle of MediCabilis™ 5% CBD ECs315 includes an oral syringe and stopper. The syringe must be regularly cleaned with soap and water.

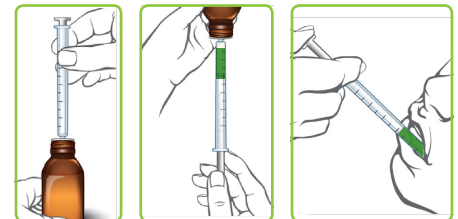
Directions:

Step 1: Remove the cap and the tamper-evident seal from the bottle. If the seal is broken, contact BOD Australia immediately by emailing pictures to info@bodaustralia.com.

Step 2: Insert the syringe into the small hole in the stopper.

Step 3: With the syringe inserted, turn the bottle upside down and extract the required amount of MediCabilis™ 5% CBD ECs315 oil into the syringe.

Step 4: Insert the syringe in the mouth and depress the plunger until the entire contents of oil are released from the syringe into the mouth for oral ingestion.



A titration period may be required to reach your optimal dose. Your doctor will provide you with a treatment schedule based on your needs. Always use MediCabilis™ 5% CBD ECs315 exactly as your doctor has told you. Do not take more than 12mL in 24 hours.

It is recommended to take MediCabilis™ 5% CBD ECs315 with or after food.

Only a doctor can start you on treatment with MediCabilis™ 5% CBD ECs315. Your doctor will assess you from time to time to see if you should continue taking it.

How long to use it

Continue to use this medicine for as long as your doctor tells you to.

Dependence is unlikely.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to use it

Do not increase dose at the same time to make up for a missed dose.

If you have trouble remembering when to use your medicine, talk to your pharmacist or doctor.

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If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much MediCabilis™ 5% CBD ECs315.

Do this even if there are no signs of discomfort or poisoning.

If you accidentally use more of this medicine than prescribed, you may:

- Feel dizzy, sleepy or confused.
- Feel your heart rate change.

If you experience any of the above symptoms, and they become concerning to you, tell your doctor or pharmacist.

5. While you are taking MediCabilis™ 5% CBD ECs315

Things you must do

- If you are about to be started on any new medicine tell your doctor that you are taking MediCabilis™ 5% CBD ECs315.
- Talk to your doctor before using this medicine if you are pregnant or plan to become pregnant.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do

- Do not give MediCabilis™ 5% CBD ECs315 to anyone else, this medicine is prescribed for you. Even if they have the same condition as you, do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Do not use MediCabilis™ 5% CBD ECs315 while breastfeeding or during pregnancy, unless advised to by your doctor.

Things to be careful of

Using MediCabilis™ with food and drink:

- Do not drink alcohol while using MediCabilis™. Using MediCabilis™ and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).
- You can take MediCabilis™ 5% CBD ECs315 with or after food.

Foreign travel with MediCabilis™

- MediCabilis™ 5% CBD ECs315 is a cannabis extract, and a controlled drug in some countries. Legal status for its use and possession may vary between countries. Check that it is legal for you to take this medicine into any countries you are travelling to and countries you are travelling through.

It is strongly recommended that you keep a copy of your doctor's contact details and business card on your person at all times for any emergency purposes.

6. Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well as a result of taking MediCabilis™ 5% CBD ECs315.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment.

You are more likely to get side effects when you start your treatment. They are usually mild and wear off within a few hours.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

A safety review conducted on MediCabilis™ 5% CBD ECs315 demonstrated no significant side effects. The most commonly experienced adverse effects observed are drowsiness (8% or 8 in 100), nausea (8% or 8 in 100), sedation (8% or 8 in 100) and altered sensory perception (8% or 8 in 100).

Tell your doctor if you notice any of the following side effects:

- problems with your memory or having trouble concentrating
- changed sense of taste or a dry mouth
- lack of energy or feeling weak or generally unwell
- feeling abnormal, sleepy or drowsy
- constipation or diarrhoea
- feeling nauseous or vomiting
- feeling depressed or disorientated
- stomach pain

Tell your doctor immediately or go to the Emergency Department at your nearest hospital if any of the following happens:

- you develop signs of allergy such as swelling of the face, lips, tongue or other part of the body
- severe dizziness or fainting
- redness, itching or rash on the skin.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects may only be found when your doctor does tests from time to time.

7. After taking MediCabilis™ 5% CBD ECs315

Storage

- Do not use MediCabilis™ 5% CBD ECs315 after the expiry date shown on the product packaging.
- Store MediCabilis™ 5% CBD ECs315 upright in its carton below 25°C. Keep away from heat and direct sunlight.
- Do not use MediCabilis™ 5% CBD ECs315 after it has been open for 60 days.
- Unless your doctor tells you to, do not keep medicines that you no longer need.
- Keep out of reach and sight of children. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

Medicines should not be disposed of via wastewater or household waste. Any unused medicine or medicine past its expiry date, as shown on the dispensing label or packaging, should be returned to the pharmacy.

8. Product description

What it looks like

MediCabilis™ 5% CBD ECs315 is a dark-green liquid packaged in a medical-grade amber 25mL and 50 mL glass bottle with a graduated syringe. The bottle is protected with a child proof and tamper-evident plastic cap.

MediCabilis™ 5% CBD ECs315 is an oral liquid which contains 5% active ingredient cannabidiol (CBD) and less than 0.2% tetrahydrocannabinol (THC).

The active ingredient in 1mL is:

50mg cannabidiol (CBD and CBDA). Less than 2mg tetrahydrocannabinol (THC).

Inactive ingredients:

Medium Chain Triglyceride Oil (MCT) sourced from coconut.

9. Sponsor details

MediCabilis™ is supplied in Australia by:

Bod Australia Ltd
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Double Bay NSW 2028
+61 (2) 9199 5018
Email: info@bodaustralia.com

bodaustralia

MediCabilis™ is a registered trademark of Bod Australia Limited.

MediCabilis™ 5% CBD ECs315 is a Non-ARTG product.

