

Lumir[®] 12.5:12.5 Balanced

Consumer Medicine Information (CMI) summary

The [full CMI](#) has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Lumir 12.5:12.5 Balanced?

Lumir 12.5:12.5 Balanced contains the active ingredients cannabidiol (12.5 mg/mL) and Δ^9 -tetrahydrocannabinol (12.5 mg/mL).

Your doctor can indicate the desired symptom or condition for which this medication has been prescribed to you.

For more information, see [1. Why am I using Lumir 12.5:12.5 Balanced?](#) in the full CMI.

2. What should I know before I use Lumir 12.5:12.5 Balanced?

This medicine is only available with a doctor's prescription. **Possession of this medication without a prescription is illegal.** Do not use if you have ever had an allergic reaction to cannabis extracts or any of the ingredients listed in [7. Product details](#).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see [2. What should I know before I use Lumir 12.5:12.5 Balanced?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lumir 12.5:12.5 Balanced and affect how it works.

More information can be found in [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Lumir 12.5:12.5 Balanced?

- Use Lumir 12.5:12.5 Balanced exactly as prescribed by your doctor, using the supplied oral syringe as per [Section 4. How do I use Lumir 12.5:12.5 Balanced?](#)
- Your doctor will assess you and find the ideal dosage for your treatment. Once the ideal dosage of Lumir 12.5:12.5 Balanced is found for your condition, continue to take that dose.
- Doses should be taken at least 6 hours apart.

More instructions can be found in [4. How do I use Lumir 12.5:12.5 Balanced?](#) in the full CMI.

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Lumir 12.5:12.5 Balanced. Tell your doctor before using this medication if:<ul style="list-style-type: none">• You are allergic to any other medications, foods, preservatives, or dyes.• You have or have had any liver, kidney, or heart problems.• If you are under 18 years of age or elderly and have difficulty completing daily tasks.• You are on any other medication, including non-prescription medication.
Things you should not do	<p>Do not use Lumir 12.5:12.5 Balanced if:</p> <ul style="list-style-type: none">• You are allergic to the ingredients that are listed in 7. Product details.• You have a serious mental health disorder. This does not include depression, anxiety, or post-traumatic stress disorder that result from your condition.• You are pregnant, planning to become pregnant, or breastfeeding, unless advised by your doctor.• You have severe heart, immune system, liver, or kidney disease, unless advised by your doctor.• Do not give or share this medicine with anyone else, even if they have the same condition as you. It is illegal to distribute Lumir 12.5:12.5 Balanced
Driving or using machines	<ul style="list-style-type: none">• Do not drive while using Lumir 12.5:12.5 Balanced. Driving under the influence of Δ^9-tetrahydrocannabinol is illegal.• Do not operate machines while using Lumir 12.5:12.5 Balanced.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol or plan to drink alcohol whilst using Lumir 12.5:12.5 Balanced.
Looking after your medicine	<ul style="list-style-type: none">• Store Lumir 12.5:12.5 Balanced upright in a dark place, away from direct sunlight at less than 25 °C.• Do not discard the supplied oral syringe, it is required for the duration of your treatment.

5. What should I know while using Lumir 12.5:12.5 Balanced?

For more information, see [Section 5. What should I know while using Lumir 12.5:12.5 Balanced?](#) in the full CMI.

6. Are there any side effects?

Common side effects of Lumir 12.5:12.5 Balanced are: drowsiness, dizziness, dry mouth, anxiety, nausea, thought impairment, increase in appetite, euphoria, blurred vision, and headache.

Immediately tell your doctor or go to the Emergency Department at the nearest hospital if you begin experiencing thoughts of self-harm or suicide, or if you begin to experience signs of an allergic reaction, such as swelling; fainting; redness, or skin irritation.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Lumir[®] 12.5:12.5 Balanced

Active ingredient(s): 12.5 mg/mL Cannabidiol and 12.5 mg/mL Δ^9 -Tetrahydrocannabinol

Consumer Medicine Information (CMI)

This leaflet answers some common questions about Lumir 12.5:12.5 Balanced. It does not contain all available information. **It does not take the place of talking to your doctor or pharmacist.**

The information in this leaflet was last updated on the date listed at the end of this CMI. More recent information may be available. Ensure that you speak to your pharmacist or doctor to obtain the most up to-date information about the medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Lumir 12.5:12.5 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 leaflet with your medicine. You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I using Lumir 12.5:12.5 Balanced?](#)
- [2. What should I know before I use Lumir 12.5:12.5 Balanced?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Lumir 12.5:12.5 Balanced?](#)
- [5. What should I know while using Lumir 12.5:12.5 Balanced?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Lumir 12.5:12.5 Balanced?

Lumir 12.5:12.5 Balanced contains the active ingredients Cannabidiol and Δ^9 -Tetrahydrocannabinol.

Lumir 12.5:12.5 Balanced is not approved for treatment of any specific conditions or symptoms. Your doctor can indicate the desired symptom or condition for which this medication has been prescribed to you.

Medicinal cannabis could be beneficial for use when suffering from debilitating conditions, including, but not limited to, chronic pain, cancer pain, chemotherapy-induced nausea and vomiting, refractory paediatric epilepsy, spasticity from neurological conditions, and anorexia or wasting associated with chronic illness.

The Therapeutic Goods Association (TGA) has provided [patient information \(PI\) for medicinal cannabis](#) concerning multiple sclerosis, chronic non-cancer pain, chemotherapy-induced nausea and vomiting in cancer (CINV), and palliative care. The TGA has also released guidance for the use of medicinal cannabis for treatment of [epilepsy in](#)

[paediatric and young adult patients](#), [multiple sclerosis](#), [nausea and vomiting](#), [chronic non-cancer pain](#), and [palliative care](#).

Lumir 12.5:12.5 Balanced contains active ingredients called cannabinoids which have been extracted from cannabis plants. Your doctor may prescribe this medication for conditions or symptoms which have not been mentioned above.

2. What should I know before I use Lumir 12.5:12.5 Balanced?

Warnings

Do not use Lumir 12.5:12.5 Balanced if:

- you are allergic to cannabidiol or Δ^9 -tetrahydrocannabinol, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you have a serious mental health disorder, such as psychosis. This does not include depression, anxiety, or post-traumatic stress disorder that result from your condition.
- you are pregnant or planning to become pregnant or breastfeeding, unless advised by your doctor.
- you have severe heart, immune system, liver, or kidney disease, unless advised by your doctor.

Check with your doctor if you:

- have any other medical conditions such as a serious mental health disorder, this does not include depression, anxiety or post-traumatic stress disorder that result from your condition.
- you have severe heart, immune system, liver, or kidney disease, unless advised by your doctor.
- take any medicines for any other condition, including non-prescription medication.
- You are allergic to any other medications, foods, preservatives, or dyes.
- you have or have had any liver, kidney, or heart problems.
- you have previously abused any drug or substance, including alcohol.
- if you are under 18 years of age or elderly and have difficulty completing daily tasks.
- you need help with transportation or driving to a medical practice or pharmacy.
- you are pregnant or planning to become pregnant or breastfeeding, unless advised by your doctor.
- you are on any other medication, including non-prescription medication

During treatment, you may be at risk of developing certain side effects. It is important 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.

Some medicines may interfere with Lumir 12.5:12.5 Balanced and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lumir 12.5:12.5 Balanced.

4. How do I use Lumir 12.5:12.5 Balanced?

How much to take / use?

- Use Lumir 12.5:12.5 Balanced exactly as prescribed by your doctor.
- To find the ideal dosage, it is highly recommended to begin at the lowest possible dose and increase slowly as ideal dosage may differ per individual. This is to allow a person to achieve the best relief, whilst minimizing side effects of the treatment. The following is a table which may be used as a guide daily dosage for the first two weeks of usage.

Weeks 1-2	1st Dose	2nd Dose	3rd Dose*	Dose/day (mL)
Day 1-2	-	0.1 mL	-	0.1 mL
Day 3-4	0.1 mL	0.1 mL	-	0.2 mL
Day 5-6	0.2 mL	0.2 mL	-	0.4 mL
Day 7-8	0.3 mL	0.3 mL	-	0.6 mL
Day 9-10	0.4 mL	0.4 mL	-	0.8 mL
Day 11-12	0.5 mL	0.5 mL	-	1.0 mL
Day 13-14	0.5 mL	0.5 mL	0.1 mL	1.1 mL
Day 15 onwards	Continue increasing the dose until therapeutic benefit is achieved or you experience side effects in consultation with your doctor.			

* Adding a 3rd dose should be determined in consultation with your doctor, as needed

When to take / use Lumir 12.5:12.5 Balanced

- Once the ideal dosage of Lumir 12.5:12.5 Balanced is found for your condition, continue to take that dose. Doses should be taken at least 6 hours apart.

How to take Lumir 12.5:12.5 Balanced with the oral syringe

1. Remove the cap from the bottle.
2. Insert the small end of the rubber stopper (packaged with the oral syringe) into the open mouth of the bottle. All 3 rings of the rubber stopper should be inside in the neck of the bottle.
3. Insert the syringe into the small hole in the stopper.
4. With the syringe inserted, turn the bottle upside down and extract the required amount of cannabis oil into the syringe.
5. Return the bottle to an upright position and remove the syringe from the stopper.
6. Insert the syringe into your mouth and press the plunger until the entire contents are released from the syringe into your mouth to swallow.

If you forget to use Lumir 12.5:12.5 Balanced

Lumir 12.5:12.5 Balanced should be used regularly at the same time each day. If you miss your dose at the usual time, you should take it as soon as you remember, provided that your doses can still be taken 6 hours apart.

If you are within 6 hours of 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 Lumir 12.5:12.5 Balanced

If you think that you have used too much Lumir 12.5:12.5 Balanced, you may need urgent medical attention.

You may experience:

- Hallucinations (auditory, smell, or visual).
- Noticeable change in heart rate.
- Feeling of confusion, drowsiness, of dizziness.

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 Lumir 12.5:12.5 Balanced?

Things you should do

Talk to your doctor if your condition worsens or does not improve.

Call your doctor straight away if you:

- Feel unwell or experience any side effects while using Lumir 12.5:12.5 Balanced

Remind any doctor, dentist, or pharmacist you visit that you are using Lumir 12.5:12.5 Balanced.

Things to be mindful of

This medicine is only available with a doctor's prescription.

Possession of this medication without a prescription is illegal and may lead to prosecution, fines, or both.

Using Lumir 12.5:12.5 Balanced with food and drink

- You may take Lumir 12.5:12.5 Balanced with or without food. Better absorption of the active ingredients may be attained when taken with high-fat foods such as avocado or peanut butter.

Travelling overseas with Lumir 12.5:12.5 Balanced

- As Lumir 12.5:12.5 Balanced is a controlled substance, the legality of its use and transport may differ between countries. As such, you should contact the Embassy or Consulate of the country or countries that you intend to visit for information on whether you may take your Lumir 12.5:12.5 Balanced.

Driving or using machines

Do not drive while using Lumir 12.5:12.5 Balanced. Driving under the influence of Δ^9 -tetrahydrocannabinol is illegal and may result in prosecution, fines, or both. Cannabis may be detected in saliva hours after taking it.

Do not operate machines while using Lumir 12.5:12.5 Balanced. Lumir 12.5:12.5 Balanced may make you feel dizzy or drowsy, which may affect your ability to perform tasks.

If you are unsure of any information or have any questions, ask your doctor or pharmacist.

Drinking alcohol

Tell your doctor if you drink alcohol. Use of alcohol and cannabis together may result in increased side effects such as impairment of your thoughts or your sense of balance.

Looking after your medicine

- Store Lumir 12.5:12.5 Balanced upright in a dark place, away from direct sunlight at less than 25 °C.
- The syringe must be cleaned regularly with soap and water.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- 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 can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Drowsiness• Dizziness• Dry Mouth• Anxiety• Nausea• Thought Impairment• Increase in appetite• Euphoria• Blurred Vision• Headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Low blood pressure• Paranoia• Depression• Failure of muscle coordination• Increased heart rate• Diarrhoea• Severe nausea or vomiting	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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.

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.

What Lumir 12.5:12.5 Balanced contains

Active ingredients (main ingredients)	Cannabidiol and Δ^9 -tetrahydrocannabinol
Other ingredients (inactive ingredients)	Medium Chain Triglyceride (MCT) oil

Do not take this medicine if you are allergic to any of these ingredients. If you are unsure or would like further information about these ingredients, speak to your doctor or pharmacist before taking this medicine.

What Lumir 12.5:12.5 Balanced looks like

Lumir 12.5:12.5 Balanced is a pale brown oil and is supplied in an amber glass 30 mL bottle with child resistant cap and a tamper evident plastic cover over the lid. **Do not use the medicine if the tamper evident plastic cover has been removed or damaged.**

The Lumir 12.5:12.5 Balanced bottle is supplied in a carton along with a stopper and a graduated oral syringe for precise dosing.

Who distributes Lumir 12.5:12.5 Balanced?

Lumir 12.5:12.5 Balanced is supplied in Australia by:

Cannim Australia Pty Ltd
Suite 406, level 4
39 East Esplanade
Manly 2095

Telephone: +61 2 9976 2467
Email: contact@cannim.com
Website: www.cannim.com

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