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 <u>full CMI</u> for further details.

1. Why am I using Lumir SX6/31?

Lumir SX6/31 contains the active ingredient Δ^9 -tetrahydrocannabinol (23.1% w/w).

Your doctor can indicate the desired symptom or condition for which this medication has been prescribed to you. For more information, see <u>1. Why am Lusing Lumir SX6/31?</u> in the full CMI.

2. What should I know before I use Lumir SX6/31?

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 <u>7. Product details</u>. **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 SX6/31? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lumir SX6/31 and affect how it works. More information can be found in <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How do I use Lumir SX6/31?

- Use Lumir SX6/31 exactly as prescribed by your doctor.
- Your doctor will assess you and find the ideal dosage for your treatment. Once the ideal dosage of Lumir SX6/31 is found for your condition, continue to take that dose.

More instructions can be found in <u>4. How do I use Lumir SX6/31?</u> in the full CMI.

5. What should	I know while using Lumir SX6/31?		
Things you	• Remind any doctor, dentist, or pharmacist you visit that you are using Lumir SX6/31.		
should do	Tell your doctor before using this medication if:		
	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	Do not use Lumir SX6/31 if:		
should not do	• You are allergic to the ingredients that are listed in <u>7. Product details</u> .		
	• 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 SX6/31.		
Driving or using	• Do not drive while using Lumir SX6/31 . Driving under the influence of Δ^9 -tetrahydrocannabinol is		
machines	illegal.		
	Do not operate machines while using Lumir SX6/31.		
Drinking alcohol	• Tell your doctor if you drink alcohol or plan to drink alcohol whilst using Lumir SX6/31.		
Looking after	• Store Lumir SX6/31 upright in a dark place, away from direct sunlight at less than 25 °C.		
your medicine			

For more information, see Section 5. What should I know while using Lumir SX6/31? in the full CMI.

6. Are there any side effects?

Common side effects of Lumir SX6/31 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 <u>6. Are there any side effects?</u> 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 <u>www.tga.gov.au/reporting-problems</u>.

Lumir[®] SX6/31

Active ingredient(s): 23.1% w/w Δ^9 -Tetrahydrocannabinol

Consumer Medicine Information (CMI)

This leaflet answers some common questions about Lumir SX6/31. 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 SX6/31 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 SX6/31?
- 2. What should I know before I use Lumir SX6/31?
- 3. What if I am taking other medicines?
- 4. How do I use Lumir SX6/31?
- 5. What should I know while using Lumir SX6/31?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Lumir SX6/31?

Lumir SX6/31 contains the active ingredient Δ^9 -tetrahydrocannabinol.

Lumir SX6/31 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, chemotherapyinduced 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, chemotherapyinduced nausea and vomiting in cancer (CINV), and palliative care. The TGA has also released guidance for the use of medicinal cannabis for treatment of <u>epilepsy in</u> paediatric and young adult patients, <u>multiple sclerosis</u>, <u>nausea and vomiting</u>, <u>chronic non-cancer pain</u>, and <u>palliative care</u>. Lumir SX6/31 contains active ingredients called cannabinoids. 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 SX6/31?

Warnings

Do not use Lumir SX6/31 if:

- you are allergic to Δ⁹-tetrahydrocannabinol, cannabidiol, 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 nonprescription 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 <u>6. Are there any side effects?</u>

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 SX6/31 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 SX6/31.

4. How do I use Lumir SX6/31?

How much to take / use?

- Use Lumir SX6/31 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 guide for finding the ideal dosage for your condition:
 - 1. Inhale once and wait 15 minutes.
 - 2. If the desired therapeutic effect does not occur, inhale twice and wait 15 minutes.
 - Continue this process increasing the number of inhalations every 15 minutes until the desired therapeutic effect occurs.

When to take / use Lumir SX6/31

 Once the ideal dosage of Lumir SX6/31 is found for your condition, continue to take that dose as per your doctor's advice.

How to take Lumir SX6/31

Take Lumir as directed by your doctor

If you forget to use Lumir SX6/31

Lumir SX6/31 should be used exactly as prescribed by your doctor.

Do not take a double dose to make up for a missed dose.

If you use too much Lumir SX6/31

If you think that you have used too much Lumir SX6/31, 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 SX6/31?

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 SX6/31.

Remind any doctor, dentist, or pharmacist you visit that you are using Lumir SX6/31.

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 SX6/31 with food and drink

• You may take Lumir SX6/31 with or without food.

Travelling overseas with Lumir SX6/31

• As Lumir SX6/31 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 SX6/31.

Driving or using machines

Do not drive while using Lumir SX6/31. 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 SX6/31. Lumir SX6/31 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 SX6/31 upright in a dark place, away from direct sunlight at less than 25 °C.

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
 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
 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 <u>www.tga.gov.au/reporting-problems</u>. 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 SX6/31 contains

Active ingredient	Δ ⁹ -tetrahydrocannabinol
(main ingredient)	
Other ingredients	Traces of other cannabinoids
(inactive ingredients)	Traces of terpenes

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 SX6/31 looks like

Lumir SX6/31 is 10 g of dried flower material and is supplied in plastic jar with child resistant cap and a tamper evident plastic ring tab. **Do not use the medicine if the tamper evident plastic ring tab has been removed or damaged**.

Who distributes Lumir SX6/31?

Lumir SX6/31 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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