

Harbour LR Day inhalation cartridge

Consumer Medicine Information (CMI) summary

The [full CMI on the next page](#) has more details. If you are concerned about using this medication, please speak to your doctor or pharmacist.

1. Why am I using Harbour LR Day inhalation cartridge?

Harbour LR Day inhalation cartridge contains the active ingredient delta-9-tetrahydrocannabinol (THC). Harbour LR Day inhalation cartridge is not approved for any specific indication and should only be used to treat specific conditions or symptoms authorised by your healthcare practitioner. For more information, see Section [1. Why am I using Harbour LR Day inhalation cartridge?](#) in the full CMI.

2. What should I know before I use Harbour LR Day inhalation cartridge?

Do not use Harbour LR Day inhalation cartridge if you have ever had an allergic reaction to cannabis or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should I know before I use Harbour LR Day inhalation cartridge?](#) in the full CMI.

3. What if I am taking other medications?

Some medications may interfere with Harbour LR Day inhalation cartridge and affect how it works. A list of these medications is in Section [3. What if I am taking other medications?](#) in the full CMI.

4. How do I use Harbour LR Day inhalation cartridge?

Use the amount of Harbour LR Day inhalation cartridge as directed by your doctor. Follow your doctor's instructions and use Harbour LR Day inhalation cartridge until your doctor tells you to stop. More instructions can be found in Section [4. How do I use Harbour LR Day inhalation cartridge?](#) in the full CMI.

5. What should I know while using Harbour LR Day inhalation cartridge?

Things you should do	• Remind any doctor, nurse, or pharmacist you visit that you are using Harbour LR Day inhalation cartridge. • You should only use Harbour LR Day inhalation cartridge under medical supervision. • Talk to your healthcare provider if you do not feel better, or if you feel worse.
Things you should not do	• You should not start taking any other medication without first informing your doctor. • You should not use this medication if you are pregnant or plan to become pregnant or are breastfeeding. • Do not stop taking this medication suddenly. • Do not take this medication to treat any other complaint unless advised by your doctor

Driving or using machines	You should not drive, operate machinery, or engage in any potentially hazardous activity under the influence of cannabis-based medications containing THC.
Drinking alcohol	- Alcohol may increase the effects of Harbour LR Day inhalation cartridge and you should avoid alcohol while taking this medication. - Alcohol taken in combination with Harbour LR Day inhalation cartridge can impair your cognitive function, coordination, reaction time, and motor skills.
Looking after your medication	Your medication should be stored in its original labelled packaging, in a safe and secure place away from children, and away from heat and direct sunlight (i.e. stored in a cool, dry place, at or below 25°C).

For more information, see Section [5. What should I know while using Harbour LR Day inhalation cartridge?](#) in the full CMI.

6. Are there any side effects?

There are several side effects possibly associated with this medication. It is important to be aware of them so that you can identify any symptoms if they occur.

Common, but usually mild side effects of cannabis-based medications include fatigue and sedation, dizziness, nausea, dry mouth, and increased appetite.

Serious side effects can include allergic reactions, convulsions, rapid heartbeat, chest pain, depression, confusion, hallucinations, psychosis, and suicidal ideation.

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.

Harbour LR Day inhalation cartridge

Consumer Medicine Information (CMI)

This leaflet provides important information about using Harbour LR Day inhalation cartridge. **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 Harbour LR Day inhalation cartridge.**

1. Why am I using Harbour LR Day inhalation cartridge?

Harbour LR Day inhalation cartridge is not approved for any specific indication and should only be used to treat specific conditions or symptoms authorised by your doctor.

Harbour LR Day inhalation cartridge is an alternative therapeutic option when all other treatment modalities have failed to show a benefit.

This medication is only available with a doctor's prescription and approval via the TGA special access scheme or authorised prescriber scheme.

The therapeutic benefit of Harbour LR Day inhalation cartridge may vary between individuals.

Ask your doctor if you have any questions about why Harbour LR Day inhalation cartridge has been prescribed for you.

2. What should I know before I use Harbour LR Day inhalation cartridge?

Warnings

Do not use Harbour LR Day inhalation cartridge:

- If you are allergic to cannabis extracts or any of the other ingredients in this product.
- If you are pregnant or breastfeeding.
- If it has expired or is damaged, please return it to your pharmacist for disposal as soon as possible.

Check with your doctor or pharmacist:

- If you have a serious heart problem such as angina, a previous history of heart attack, poorly controlled high blood pressure, or a problem with your heart rate or heartbeat.
- If you have a personal history of serious mental disorders such as schizophrenia or psychosis unless specifically prescribed by a qualified healthcare provider aware of your psychiatric disorder.
- If you have epilepsy or regular fits (seizures).
- If you have serious liver or kidney disease.
- If you are less than 18 years of age.
- If you have previously abused any drug or substance

There may be other contraindications not yet known due to limited scientific information.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

3. What if I am taking other medications?

Tell your doctor or pharmacist if you are taking any other medications, including any medications vitamins or supplements 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 Harbour LR Day inhalation cartridge. If you see a different doctor or go to hospital, let them know all the medications you are taking.

Some medications may interfere with Harbour LR Day inhalation cartridge and affect how it works.

These medications include warfarin and other blood thinners, strong painkillers, and other medications used for anxiety, depression, epilepsy, and sleep aids. This list is not exhaustive. If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Harbour LR Day inhalation cartridge.

Avoid taking Harbour LR Day inhalation cartridge with alcohol and/or other CNS depressants/sedatives including prescription medications, e.g., benzodiazepines. Using Harbour LR Day inhalation cartridge at the same time as alcohol and/or other sedative drugs may cause more severe levels of impairment and adverse effects.

Check with your doctor or pharmacist if you are not sure about what medications, vitamins or supplements you are taking and if these could potentially affect the therapeutic benefits of Harbour LR Day inhalation cartridge.

4. How do I use Harbour LR Day inhalation cartridge?

How much to take / use

- Harbour LR Day inhalation cartridge can be taken on a metered dosage schedule or as needed (PRN) as determined by your healthcare provider.
- A titration period may be required to reach your optimal dose.
- The amount of Harbour LR Day inhalation cartridge you use each day will depend on your response and tolerability to the product.
- Your doctor will provide you with a treatment schedule based on your needs.
- Always use Harbour LR Day inhalation cartridge exactly as instructed by your healthcare provider. Check with your healthcare provider or pharmacist if you are not sure.
- While using Harbour LR Day inhalation cartridge, you must be under medical supervision to help you determine if the product is working for you or if you experience any side-effects from the treatment.
- Effects from Harbour LR Day inhalation cartridge may begin within approximately 60-90 minutes after you take a dose and may last for approximately 6-9 hours, depending on the dosage and how long you have been taking this medication, and your individual response.
- Do not exceed the recommended dosage.

Follow these instructions to take the medication:

- Open the container & remove the cartridge.
- Attach the cartridge to a 510 threaded battery (purchased separately)
- Switch battery device on. If battery has a pre-heat setting, use this to reduce chances of clogging.
- Inhale for 3-5 seconds, then exhale
- Wait 20 minutes to see if the effects are aiding with your symptoms.

When to take / use Harbour LR Day inhalation cartridge

- Harbour LR Day inhalation cartridge should only be used as directed by your doctor.
- This product can be taken with or without food, but the efficacy may be enhanced when taken with fatty food.

If you use too much Harbour LR Day inhalation cartridge

If you think that you have used too much Harbour LR Day inhalation cartridge, 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 Harbour LR Day inhalation cartridge?

Things you should do:

- Take Harbour LR Day inhalation cartridge as your doctor has prescribed.
- Remind any doctor or pharmacist you visit that you are using Harbour LR Day inhalation cartridge.
- Tell your doctor if your symptoms do not improve.

Call your doctor straight away if you:

- Are pregnant or become pregnant while taking Harbour LR Day inhalation cartridge.

Things you should not do:

- Do not stop using this medication suddenly without telling your doctor. If you stop taking it suddenly or change the dose, your condition may worsen, or you may experience unwanted side effects.
- Do not use Harbour LR Day inhalation cartridge to treat any other complaints unless your doctor tells you to.
- Do not give your medication to anyone else, even if they have the same condition as you.

Driving or using machines:

Do not drive or use machinery after taking Harbour LR Day inhalation cartridge.

Harbour LR Day inhalation cartridge may cause you to feel sleepy or dizzy and can also slow cognitive function. This can lead to decreased concentration and coordination, slowed reaction time, and impaired motor skills. These effects may be increased if taking other medication.

Drinking alcohol:

Tell your doctor or pharmacist if you drink alcohol.

You should avoid alcohol while using Harbour LR Day inhalation cartridge since alcohol may increase the effects of Harbour LR Day inhalation cartridge and this could impair cognition, reaction time, coordination, and motor skills.

Travelling overseas with Harbour LR Day inhalation cartridge:

Before going to a foreign country check if it is legal for you to travel with Harbour LR Day inhalation cartridge. This includes any countries that you will be traveling through to get to your final destination.

Looking after your medication:

- Store below 25°C, away from direct sunlight in a cool and dry place.
- Always keep your medication in its original packaging until it is time to take it.
- Refer to the product label for expiration dates.
- **Keep out of reach of children.**

Getting rid of any unwanted medication:

If you no longer use this medication or it is out of date, take it to any pharmacy for safe disposal. Do not use this medication after the expiry date.

6. Are there any side effects?

All medications 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. Other side effects not listed here may occur in some people. **Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Less serious side effects	What to do
• Daytime drowsiness • Dizziness • Fatigue • Dry mouth • Dry eyes • Headache • Increased appetite • Difficulty concentrating • Nausea • Memory Impairment • Blurred Vision • Constipation or diarrhoea • Euphoria	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
Serious side effects	What to do
Allergy-related: • Swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in breathing. • Shortness of breath or difficulty in breathing • Skin reaction which may include rash, itching, redness, blistering or peeling of the skin. Cardiovascular: • Rapid heartbeat • Chest pain • Low blood pressure/feeling faint Brain/Nervous system: • Convulsions • Numbness • Burning sensation • Vomiting • Loss of coordination balance • Disorientation • Confusion • Depression • Agitation • Hallucinations • Psychosis • Thoughts of suicide General: • Upper respiratory infection • Strong abdominal pain	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.

7. Product details

What Harbour LR Day inhalation cartridge looks like

Harbour LR Day inhalation cartridge is provided as a 2g cartridge of dark to light, yellow to gold liquid.

What Harbour LR Day inhalation cartridge contains

Active Ingredients

Delta-9-Tetrahydrocannabinol (THC) – 1600 mg (800 mg/g)

Cannabigerol (CBG) – 90 mg (45 mg/g)

Cannabinol (CBN) – 50 mg (25 mg/g)

Inactive Ingredients

N/A

xw

Who distributes Harbour LR Day inhalation cartridge

Aura Therapeutics Pty Ltd.

Melbourne Business Centre

Ground Floor, 470 St Kilda Road,

Melbourne, VIC, 3004.

Email: info@auratherapeutics.com.au

Website: www.auratherapeutics.com.au

Harbour LR Day inhalation cartridge is a **Schedule 8 Controlled Drug**, POSSESSION WITHOUT AUTHORITY IS ILLEGAL, KEEP OUT OF REACH OF CHILDREN

Harbour LR Day inhalation cartridge is not listed on the Australian Register of Therapeutic Goods (ARTG) and can only be accessed via the Special Access Scheme (B) from an Authorised Prescriber or a registered clinical trial participant.