

Consumer Medicine Information (CMI)

LGP CLASSIC product range

LGP CLASSIC 1:20

LGP CLASSIC 10:10

LGP CLASSIC 20:5

Medicinal Cannabis Oil Oral Liquid Products

What is in this leaflet

Please read this leaflet carefully before you start using LGP CLASSIC medicinal cannabis oil.

This leaflet answers some common questions about LGP medicinal cannabis oil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using LGP medicinal cannabis oil against the benefits he or she expects it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What LGP medicinal cannabis oil is used for

LGP medicinal cannabis oil is for oral use. It is made from whole plant extract containing full spectrum cannabinoids. The major cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

There is growing evidence that medicinal cannabis may have a role in several medical conditions. These include intractable chronic pain insufficiently responsive to other analgesics, pain associated with spasticity in multiple sclerosis (MS), pain associated with cancer in palliative care, nausea and vomiting caused by cancer treatment, appetite loss, sleep disturbance, post-traumatic stress disorder (PTSD), body wasting, anxiety and refractory epilepsy. Your doctor may have prescribed LGP medicinal cannabis oil for another reason.

Ask your doctor if you have any questions about why LGP medicinal cannabis oil has been prescribed for you.

The potential therapeutic and adverse effects associated with medicinal cannabis use may vary depending on the amount of medicinal cannabis used and the medical condition.

LGP medicinal cannabis oil is an unregistered medicine. It is only available for use by you, following approval from the Australian Therapeutic Goods Administration (TGA) Special Access Scheme, for your doctor to prescribe for you.

How LGP medicinal cannabis oil works

The exact mechanism and magnitude of effects of THC and CBD are not fully understood. The THC and CBD in LGP medicinal cannabis oil act on very specific targets in the body, known as cannabinoid receptors. These receptors are found naturally throughout the body, in most tissues and organs, but they are especially numerous in the brain and nervous system.

Before you take LGP medicinal cannabis oil

Your doctor will assess the suitability and dose of LGP medicinal cannabis oil for your clinical condition against the effectiveness of currently approved medicines.

When to use it with caution

Use LGP medicinal cannabis oil with caution if:

- you have liver, kidney, heart or lung disease
- you have a family history of serious mental disorders such as schizophrenia, psychosis, depression, or bipolar disorder
- you have a history of alcohol or drug abuse or substance dependence

When you must not use it

Do not use LGP medicinal cannabis oil if:

- you are allergic to any cannabinoid products.
- you have a personal history of schizophrenia or psychosis

Do not take LGP medicinal cannabis oil if you are pregnant, are planning to get pregnant, or are breastfeeding.

Talk to your doctor if you are not sure whether you should start using LGP medicinal cannabis oil.

Do not take LGP medicinal cannabis oil after the expiry date has passed.

Do not take LGP medicinal cannabis oil if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking LGP medicinal cannabis oil, contact your doctor or pharmacist.

Before you start to use LGP medicinal cannabis oil

Tell your doctor if you:

- have allergies to any other medicines
- have allergies to cannabis, or any other substances such as foods, preservatives or dyes
- are pregnant, planning to get pregnant or breastfeeding
- have a personal or family history of serious mental disorders such as schizophrenia, psychosis, depression, or bipolar disorder

If you have not told your doctor about any of the above, tell them before you start using LGP medicinal cannabis oil.

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, health food shop or other supplier.

You should also tell any health professional who is prescribing a new medication for you that you are taking LGP medicinal cannabis oil. Some medicines may interfere with LGP medicinal cannabis oil. These include:

- Any drugs which slow down the central nervous system, causing drowsiness. These may include sleeping pills, sedatives, some pain medicines, some allergy or cold medicines, antiepileptic medicines or alcohol.
- Other drugs may include antiretroviral drugs used in the treatment of HIV/AIDS, certain antidepressants, stomach acid inhibitors, certain antibiotics and antifungal medicines, certain medicines for the heart and herbal medicines like Saint John's Wort.

These medicines may be affected by LGP medicinal cannabis oil or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking LGP medicinal cannabis oil.

How to take LGP medicinal cannabis oil

How and when to take it

LGP medicinal cannabis oil is for oral use only. Use the 1mL oral syringe provided to measure the dose prescribed by your doctor. Follow the dosing instructions on the pharmacy label.

There is not yet a scientifically defined dose of medicinal cannabis for any specific medical condition. **If you have not consumed medicinal cannabis before, it would be prudent to have someone with you the first time you use it.**

Your doctor will work with you to decide the dose of LGP medicinal cannabis oil that best suits you and your symptoms and minimises any unwanted side effects.

Follow all directions given to you by your doctor and pharmacist.

Your doctor will guide you how to start with a very low dose using the approach of "Start Low, Go Slow". You and your doctor will monitor the product's effectiveness and unwanted side effects. Wait a minimum of 6 to 8 hours between each dose to assess effectiveness and to reduce the potential for unwanted side effects.

How long to take LGP medicinal cannabis oil

Your doctor will advise how long you need to take LGP medicinal cannabis oil.

If you forget to take it

Wait until the next dose is due. **Do not take a double dose to make up for the dose that you missed.** This may increase the risk of getting an unwanted side effect.

In case of overdose

If you take too much (overdose)

If you think that you or anyone else may have taken too much LGP medicinal cannabis oil, immediately telephone your doctor and/or the Poisons Information Centre (telephone 13 11 26, which is available 24 hours every day), or go to the Emergency Department at your nearest hospital.

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

Symptoms of overdose may include sleepiness, confusion, disorientation, clumsiness or loss of coordination, fainting, dizziness, chest pain, fast, slow or pounding heartbeat, panic attacks, loss of contact with reality and seizures.

While using LGP medicinal cannabis oil

Things you must do

Stop using LGP medicinal cannabis oil immediately and consult your doctor if you begin to experience any side effects (see side effects section for additional information).

If you are about to be started on any other new medicine tell your doctor and pharmacist that you are taking LGP medicinal cannabis oil.

Things you must not do

Do not give LGP medicinal cannabis oil to anyone else, even if they have the same condition as you.

ALLERGY WARNING

Do not use if you are allergic to cannabis products.

DO NOT DRIVE OR OPERATE MACHINERY WHILE TAKING LGP medicinal cannabis oil.

Check with your doctor when it is safe to drive after stopping taking LGP medicinal cannabis oil.

Things to be careful of

LGP medicinal cannabis oil may make you feel drowsy or sleepy.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using LGP medicinal cannabis oil. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

The information on side effects associated with therapeutic use of medicinal cannabis is limited. **Tell your doctor or pharmacist if you notice any of the following side effects.** Some of the more

well-known side effects of medicinal cannabis are intoxication-like reactions including:

- dizziness, drowsiness, feeling faint or lightheaded, feeling tired;
- feeling elated or euphoric – ‘on a high’, feeling confused, having hallucinations (seeing or hearing things that do not exist)
- feeling suspicious or paranoid;
- dry mouth, feeling sick, vomiting, or diarrhoea;
- increase or decrease in appetite;
- fast heartbeat.

Other adverse effects not listed above may also occur in some patients. **Tell your doctor if you notice any other effects.**

Patients and carers can report a side effect by telephone and are encouraged to speak to a pharmacist from [NPS MedicineWise](#) on 1300 134 237. The pharmacist can provide further advice on how to manage the side effect and lodge a report.

Consumers, patients, carers and healthcare professionals are encouraged to report serious side effects (also called adverse drug events) to the Therapeutic Goods Administration (TGA) via the website ***TGA online, Adverse Event Reporting*** by registering and completing the report at www.tga.gov.au/reporting-problems

Storage of LGP medicinal cannabis oil

Storage

Store below 25°C. Protect from light. Keep it safe where children cannot reach it.

Expiry

The expiry date is shown on the bottle label.

Disposal

Return any unused or expired LGP medicinal cannabis oil to a pharmacy for safe disposal.

Product description

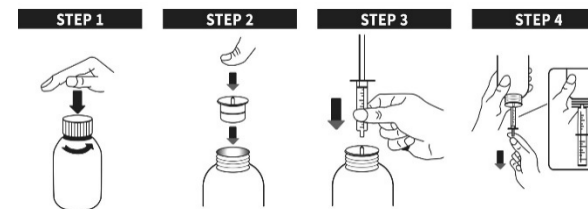
What it looks like

The medicine is a clear, colourless to yellow or amber oil, supplied in a 50mL or 100mL amber glass bottle with a tamper-evident, child resistant cap.

LGP CLASSIC products are natural, whole plant products. Slight variation in appearance may occur between batches. A 1mL oral syringe, press-in adapter and end cap are provided for dosing the medicine.

Instructions for administration. (See diagram)
If you need help, ask your pharmacist or other healthcare professional.

1. Remove the cap from the bottle (press down and turn).
2. Insert the small end of the rubber stopper into the open mouth of the bottle (all three rings of the rubber stopper should be inside the neck of the bottle).
3. Insert syringe into the small hole in the stopper firmly but without using too much force.
4. Turn the bottle upside down to extract the required amount of cannabis oil into the syringe.
5. When finished, wash the syringe and plunger before capping and storing.



Each product contains the active ingredients listed in one millilitre (1mL) of oil:

LGP CLASSIC 1:20

delta-9-tetrahydrocannabinol (THC)	1 mg
cannabidiol (CBD)	20 mg

LGP CLASSIC 10:10

delta-9-tetrahydrocannabinol (THC)	10 mg
cannabidiol (CBD)	10 mg

LGP CLASSIC 20:5

delta-9-tetrahydrocannabinol (THC)	20 mg
cannabidiol (CBD)	5 mg

Inactive ingredients of LGP medicinal cannabis oil

The active ingredients are dissolved in medium chain triglycerides (MCT) oil.

LGP CLASSIC medicinal cannabis oil does not contain added gluten, lactose, sugars, preservatives or flavourings.

Sponsor Details

LGP medicinal cannabis oil is manufactured in Australia and supplied by:

Little Green Pharma Ltd
PO Box 690
West Perth WA 6872
Australia

Phone: (08) 6280 0050

Email: info@lgpharma.com.au

Product Codes

LGP CLASSIC 1:20	CC-0120-50 / CC-0120-100
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LGP CLASSIC 10:10	CB-1010-50 / CB-1010-100
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LGP CLASSIC 20:5	CT-2005-50 / CT-2005-100
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