

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LAMPRENE® 50 and 100 mg soft gelatin capsules

Sugar free

Read all of this leaflet carefully before you start taking LAMPRENE 50/100 mg soft gelatin capsules:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LAMPRENE 50/100 mg soft gelatin capsules has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LAMPRENE 50/100 mg soft gelatin capsules is and what it is used for
2. What you need to know before you use LAMPRENE 50/100 mg soft gelatin capsules
3. How to use LAMPRENE 50/100 mg soft gelatin capsules
4. Possible side effects
5. How to store LAMPRENE 50/100 mg soft gelatin capsules
6. Contents of the pack and other information

1. WHAT LAMPRENE 50/100 MG SOFT GELATIN CAPSULE IS AND WHAT IT IS USED FOR:

Leprosy:

LAMPRENE 50/100 mg soft gelatin capsule is an anti-mycobacterial medicine that stops the growth of mycobacteria in the body and/or eventually kills them. LAMPRENE 50/100 mg soft gelatin capsule is used to treat leprosy, and is given together with other medicines for leprosy.

LAMPRENE 50/100 mg soft gelatin capsule should never be used alone for the treatment of leprosy. Multidrug therapy (MDT) is necessary to prevent the emergence of drug resistance.

Multidrug resistant Tuberculosis (MDR-TB):

LAMPRENE 50/100 mg soft gelatin capsule is used in the treatment of pulmonary multidrug-resistant tuberculosis, MDR-TB in adults and children 10 years and older including, rifampicin resistant tuberculosis (RR-TB). It is used in combination with anti-TB medicines.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LAMPRENE 50/100 MG SOFT GELATIN CAPSULE:

Follow all the doctor's instructions carefully.

Do not take LAMPRENE 50/100 mg soft gelatin capsule:

- if you are hypersensitive or allergic to clofazimine or any of the other ingredients of LAMPRENE 50/100 mg soft gelatin capsule;
- If you are allergic (hypersensitive) to peanuts or soya, do not use LAMPRENE 50/100 mg soft gelatin capsule since it contains soybean oil;
- If you have a personal or family history of a heart problem called "congenital long QT syndrome";
- If you are taking other medicines known to prolong QTc interval up to the time intervals known to cause serious heart rhythm disorders (dysrhythmias).

If any of these apply to you, tell your doctor without taking LAMPRENE 50/100 mg soft gelatin capsule.

If you think you may be allergic, ask your doctor for advice.

Warnings and precautions:

- If you have frequent stomach pain

- If you have continuous diarrhoea or vomiting
- If you have heart, liver or kidney disease
- If you have hepatitis B or C
- If you are pregnant or breastfeeding your baby
- If you are taking QT-prolonging medicines such as bedaquiline, fluoroquinolones, delamanid, azithromycin, rilpivirine, lopinavir, atazanavir, nelfinavir, saquinavir.

If any of these apply to you, tell your doctor before taking LAMPRENE 50/100 mg soft gelatin capsule.

Safety and efficacy in children and patients treated for HIV have not been established.

Tell your doctor straight away:

- If your symptoms do not improve within 2 to 3 months, or if they become worse. It may take up to 6 months before the full benefit of this medicine is seen.
- An inflammatory skin reaction may occur with the use of LAMPRENE 50/100 mg soft gelatin capsule. This is usually reversible and responds well to anti-inflammatory medicines.
- The active substance of LAMPRENE 50/100 mg soft gelatin capsule is red and this may discolour your skin and hair within a few weeks after you start taking it. This reddish to dark brown discoloration will go away when you stop taking LAMPRENE 50/100 mg soft gelatin capsule, though it may take several months or years to clear up completely. If skin discoloration causes you to feel depressed, see your doctor. LAMPRENE 50/100 mg soft gelatin capsule may also cause discoloration of the conjunctiva, tears, sweat, spit, urine, stools, nasal secretions, semen and breast milk.

LAMPRENE 50/100 mg soft gelatin capsule should never be used alone for the treatment of leprosy or MDR-TB (see section 3 How to use LAMPRENE 50/100 mg soft gelatin capsules). Multi-drug therapy is necessary to prevent the emergence of resistance to LAMPRENE 50/100 mg soft gelatin capsule and other medicines used to treat leprosy or MDR-TB.

Always take your medicines as prescribed by your healthcare professional.

Other medicines and LAMPRENE 50/100 mg soft gelatin capsule:

Always tell your healthcare professional if you are taking any other medicines. This includes complementary or traditional medicines.

- Dapsone- May reduce the anti-inflammatory activity of LAMPRENE 50/100 mg soft gelatin capsule. If leprosy-associated inflammatory reactions develop when taking dapsone and LAMPRENE 50/100 mg soft gelatin capsule, it is still advisable to continue treatment with both medicines.
- Rifampicin- clofazimine in LAMPRENE 50/100 mg soft gelatin capsule may reduce rifampicin absorption in leprosy patients.
- Isoniazid- If you are taking high doses of LAMPRENE 50/100 mg soft gelatin capsule (300 mg daily) and isoniazid (300 mg daily), there may be higher than normal levels of clofazimine in your blood plasma and urine.
- LAMPRENE 50/100 mg soft gelatin capsule may increase the QT interval of your electrocardiogram (ECG) causing heart rhythm disturbances. Tell your doctor if you think this is happening to you.
- QT prolonging medicines such as bedaquiline, azithromycin and fluoroquinolones. Caution is recommended when LAMPRENE 50/100 mg soft gelatin capsule is taken with other medicines with known QT interval prolonging potential.
- Caution should be exercised when taking LAMPRENE 50/100 mg soft gelatin capsule together with medicines such as TB medicines (bedaquiline, delamanid, clarithromycin), selected unboosted anti-retrovirals (amprenavir, delaviridine, efavirenz, etravirine, indinavir, nelfinavir, raltegravir, rilpivirine, simeprevir, maraviroc), medicines to lower your blood pressure and cholesterol (simvastatin, lovastatin, losartan, verapamil, diltiazem, nitrendipine, amlodipine, nislodipine, nifedipine, eplerenone, felodipine, lercanidipine), medicines to reduce blood sugar levels (pioglitazone, repaglinide, saxagliptin).

Taking LAMPRENE 50/100 mg soft gelatin capsule with food and drink:

Take the capsules at mealtimes or with a drink of milk.

Pregnancy, breastfeeding and fertility:

The safe use of LAMPRENE 50/100 mg soft gelatin capsule in pregnancy has not been established.

The active substance of LAMPRENE 50/100 mg soft gelatin capsule crosses the placenta.

Skin discolouration of your baby may occur if Lamprene 50/100 mg soft gelatin capsules were used during pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The active substance of LAMPRENE 50/100 mg soft gelatin capsule (clofazimine) passes into the breast milk and skin discolouration may occur in the infant. If you are taking LAMPRENE 50/100 mg soft gelatin capsule, you should not breast-feed your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery:

LAMPRENE 50/100 mg soft gelatin capsule can cause dizziness, tiredness, headache or eyesight problems. If you experience any of these undesirable effects, do not drive, use machines, or perform other tasks that require your attention.

It is not always possible to predict to what extent LAMPRENE 50/100 mg soft gelatin capsule may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LAMPRENE 50/100 mg soft gelatin capsule affects them.

3. HOW TO TAKE LAMPRENE 50/100 mg soft gelatin capsule

Do not share medicines prescribed for you with any other person. It may harm them.

Always take LAMPRENE 50/100 mg soft gelatin capsule exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not exceed the recommended dose.

It is very important to keep taking LAMPRENE for the full treatment period, even if you begin to feel better after a few months. You may have to take it regularly for as long as 12 months, as prescribed by your doctor. If you stop taking LAMPRENE too soon, your symptoms may return.

Your doctor will prescribe the correct dosage for you, if there is uncertainty consult your doctor.

How much LAMPRENE 50/100 mg soft gelatin capsule to take

You should only take LAMPRENE 50/100 mg soft gelatin capsule should only be taken if prescribed by your doctor. He or she will tell you exactly how many capsules of LAMPRENE 50/100 mg soft gelatin capsule to take.

Leprosy:

For the treatment of leprosy, adult patients usually take 300 mg LAMPRENE 50/100 mg soft gelatin capsule under supervision once a month and 50 mg LAMPRENE 50/100 mg soft gelatin capsule once daily, together with other medicines against leprosy. Children (10 to 14 years) usually take 150 mg LAMPRENE 50/100 mg soft gelatin capsule under supervision once a month and 50 mg every other day, together with other medicines against leprosy. For children less than 10 years, your doctor will decide on the most suitable dosage.

Treatment of children below 10 years of age is possible only if dapsone tablets of 25 mg are commercially available.

Multidrug-Resistant (MDR) TB:

For the treatment of MDR-TB, adult's patient weighing at least 30 kg, the recommended dosage is 100 mg/day and adults weighing less than 30 kg, the recommended dosage is 50 mg/day.

Children (10 years of age and over) weighing at least 30 kg, usually are given 2-5 mg/kg/day, not exceeding 100 mg/day. For children weighing less than 30 kg, the recommended dosage is 2-5 mg/kg/day, not exceeding 50 mg/day. If a dose lower than 50 mg/day is required, the 50 mg dose can be given every other day.

When to take LAMPRENE 50/100 mg soft gelatin capsule

LAMPRENE 50/100 mg soft gelatin capsule works best when there is a constant amount of the active substance in the blood. To help keep the amount constant, do not miss any doses.

If you take more LAMPRENE 50/100 mg soft gelatin capsule than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Show the pack of **LAMPRENE 50/100 mg soft gelatin capsule**.

Medical treatment may be necessary.

If you forget to take LAMPRENE 50/100 mg soft gelatin capsule

If you have forgotten to take a dose of LAMPRENE 50/100 mg soft gelatin capsule as scheduled, take it as soon as you remember and then go back to your normal dosing schedule. However, if it is almost time for the next dose, do not take a double dose of LAMPRENE 50/100 mg soft gelatin capsule to make up the one that you missed and continue your treatment as usual.

How long to take LAMPRENE 50/100 mg soft gelatin capsule

It is very important to keep taking LAMPRENE 50/100 mg soft gelatin capsule for the full treatment period, even if you begin to feel better after a few months. You may have to take it regularly for as long as 12 months, as prescribed by your doctor. If you stop taking LAMPRENE 50/100 mg soft gelatin capsule too soon, your symptoms may return.

Continue taking LAMPRENE 50/100 mg soft gelatin capsule as your doctor tells you.

If you have questions about how long to take LAMPRENE 50/100 mg soft gelatin capsule, talk to your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

LAMPRENE 50/100 mg soft gelatin capsule can have side effects. Not all side effects reported for LAMPRENE 50/100 mg soft gelatin capsule are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LAMPRENE 50/100 mg soft gelatin capsule, please consult your doctor, pharmacist or other healthcare professional for advice.

Some effects could be serious

You could experience heart rhythm disturbances e.g.

- irregular heart beat (fast or slow)
- dizziness and/or fainting
- shortness of breath
- severe tiredness

- If the skin and hair discolouration has a serious impact on your quality of life and make you feel depressed
- If you experience upper stomach pain (you may also have fever, chills, chest and left shoulder pain, feel nauseous or vomit)
- If you have a blurred or cloudy vision
- If you have a bowel obstruction (blockage)
- If you have black stools (symptoms of stomach or intestine bleeding)
- If you feel generally unwell, nauseous, vomit, experience a loss of appetite, fever (symptoms of hepatitis)
- If you have serious skin reactions with flaking or peeling

If you experience any of these, **tell your doctor straight away.**

Some side effects are frequent

- Reddish to dark-brown discolouration of the skin, hair and eyes (reversible)
- Discolouration of sweat, saliva, tears, urine and stools
- Gastrointestinal disorders (nausea, vomiting, diarrhoea)
- Stomach pain or discomfort
- Dry, rough or scaly skin

If any of these affects you severely, **tell your doctor.**

- Dry, burning, itching, or irritated eyes
- Eyesight problems
- Skin rash and itching

- Weight loss

If any of these affects you severely, tell your doctor.

Some side effects are less frequent

- Headache
- Loss of appetite
- Increased sensitivity of the skin when exposed to sunlight
- Acne-like skin reactions
- Tiredness
- Swollen lymph nodes
- Dizziness
- Constipation
- Jaundice (yellowing of the skin and eyes)
- Fever

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LAMPRENE 50/100 mg soft gelatin capsule.

5. HOW TO STORE LAMPRENE 50/100 mg soft gelatin capsule

Store at or below 25 °C in the original package. Protect the capsules from moisture and heat.

Store all medicines out of reach of children.

Remember to take back any unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not use after the expiry date shown on the box.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What LAMPRENE 50/100 mg soft gelatin capsule contains

The active substance is 50 or 100 mg of micronized clofazimine suspended in an oil-wax base.

The other ingredients are:

Capsules: Butylated hydroxytoluene, Citric acid, anhydrous, Propylene glycol, Rapeseed oil, refined, Lecithin (E322), Soybean oil, hydrogenated, Soya-bean oils, partially hydrogenated.

Capsule shells: Black iron oxide (E172, Ethyl parahydroxybenzoate sodium, Ethylvanillin, Gelatin, Glycerol 85 %), p-Methoxy acetophenone, Propyl parahydroxybenzoate sodium, Red iron oxide (E172).

What LAMPRENE 50/100 mg soft gelatin capsule looks like and contents of the pack

LAMPRENE 50 mg soft gelatin capsule: Spherical, brown, opaque soft gelatin capsules with no imprint on the capsules. Diameter approximately 7,2 mm.

LAMPRENE 100 mg soft gelatin capsule: Brown, opaque, oblong, soft gelatin capsules. One side carries the imprint "GEIGY", the other side carries imprint "GM" in white. Diameter approximately 6,5 mm.

LAMPRENE 50/100 mg soft gelatin capsules are either packaged in white to off-white high-density polyethylene (HDPE) bottles with a HDPE screw cap with a yellow tamper proof ring, further packaged in paper board carton or can be packaged in low density polyethylene (LDPE) bags inserted in high density polyethylene (HDPE) bottle with a HDPE screw cap.

Kindly note that not all strengths may be marketed.

Holder of Certificate of Registration:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Jukskei View

Waterfall City

Johannesburg

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