

Lamprene(R)

clofazimine (kloe FA zi meen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lamprene.

It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lamprene against the benefits it can provide you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Lamprene is used for

Lamprene is used to treat leprosy (Hansen's disease) and is given together with other medicines for leprosy.

Lamprene should never be used alone for the treatment of leprosy

Multidrug therapy is necessary to prevent the bacteria that causes leprosy (called Hansen's bacillus or Mycobacterium leprae) from developing resistance to the treatment.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Lamprene is only available with a doctor's prescription. It is not addictive.

Before you take Lamprene

When you must not take it

Do not take Lamprene if you are allergic (hypersensitive) to:

- * clofazimine (the active ingredient)
- * peanuts or soya (since this medicinal product contains soybean oil)
- * any of the other ingredients of Lamprene listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- * shortness of breath, wheezing or difficulty breathing
- * swelling of the face, lips, tongue or other parts of the body
- * rash, itching or hives on the skin.

If any of these apply to you, do not take Lamprene and tell your doctor.

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

Do not take Lamprene after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have any of the following medical conditions:

- * liver or kidney problems
- * continuous or frequent abdominal pain, diarrhoea, or vomiting.

Your doctor will take these into account before and during your treatment with Lamprene.

Tell your doctor if you are pregnant or intend to become pregnant.

If possible, Lamprene should be stopped at least 3 months before an intended pregnancy.

You should only use Lamprene during pregnancy if your doctor advises you to do so.

The active substance in Lamprene crosses the placenta. This medicine may affect your developing baby if

you take it while you are pregnant, especially during the first 3 months.

The baby may also develop a red to brownish-black discolouration of the skin. This is reversible but it may last a long time.

Tell your doctor if you wish to breast-feed while you are taking Lamprene.

The active ingredient passes into breast milk and your baby's skin may become discoloured. Mothers taking Lamprene should not breast feed unless advised by the doctor.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor or pharmacist about any of these things, tell him/her before you have Lamprene.

Taking other medicines

Tell your doctor or pharmacist if you are taking:

- * Isoniazid, a medicine used to prevent or treat tuberculosis
- * any other medicines, including ones that you buy without a prescription from a pharmacy, supermarket or health food store.

If you have not told your doctor about any of these things, tell him/her before you start taking Lamprene.

How to take Lamprene

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

These instructions may differ from the information contained in this leaflet.

Lamprene works best when there is a constant amount of the active substance in the blood.

Do not miss any doses.

This will help to keep the amount of the active in your bloodstream constant.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Adults usually take one 50 mg capsule of Lamprene each day plus one extra dose of 300 mg under supervision once a month. Dapsone and rifampicin will also be taken according to your doctor's instructions.

Children receive lower doses according to their body weight.

Do not exceed the recommended dose.

When to take Lamprene

Take Lamprene capsules during meals or with milk to prevent a stomach upset.

How long to take it

Continue taking Lamprene for as long as your doctor tells you to.

This may be for as long as two years.

If you want your leprosy to clear up completely, you must take this medicine for the whole treatment period, even if you feel better after a few months.

If you stop taking Lamprene too soon, your symptoms may return.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Center (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Lamprene. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Medical treatment may be necessary.

Some symptoms of an overdose may include:

- * dizziness
- * headache
- * nausea (feeling sick)
- * vomiting
- * stomach pains
- * diarrhoea
- * reduction in urine passed
- * discolouration of the skin and urine.

Show the pack of Lamprene to any medical staff that may be attending to you/the affected patient.

While you are taking Lamprene

Things you must do

If you become pregnant while taking Lamprene, tell your doctor.

Your doctor can discuss with you the risks of taking it while you are pregnant.

If skin discoloration causes you to become depressed while taking this medicine, discuss this with your doctor.

Sometimes during treatment, people become depressed because of the skin discolouration that Lamprene

can cause. The active substance of Lamprene 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, though it may take several months or years to clear up completely.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen.

Lamprene may cause your skin to be more sensitive to sunlight than it normally is. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

If your skin appears to be burning more readily, tell your doctor.

Remind your doctor and pharmacist that you are taking Lamprene if you are about to be started on any new medicine.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Lamprene.

Things you must not do

Do not use a sunlamp.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Lamprene affects you.

In some people, this medicine can cause:

- * headache
- * tiredness
- * dizziness
- * dimness of vision or eyesight problems.

Make sure you know how it affects you before you drive a car, operate machinery, or do anything else that could be dangerous or

requires your attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lamprene, even if you do not think it is connected with the medicine.

Like all medicines, Lamprene can cause side effects, although not everybody gets them. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following rare but serious side effects:

- * severe pains in the stomach or abdomen
- * yellowing of the skin or eyes
- * fever or chills
- * chest and left shoulder pain
- * bloody or persistent diarrhoea
- * nausea, loss of appetite
- * vomiting, especially blood or material that looks like coffee grounds
- * bleeding from the back passage, black sticky bowel motions (stools)
- * flaking or peeling skin
- * blurred or cloudy vision

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * reversible red to brownish-black discolouration of the skin, eyes and hair, especially if you are light-skinned
- * discoloured sweat, tears, saliva, semen, breast milk, urine and bowel motions; note that once the medicine is stopped, the discolouration will disappear but

it may take several months or years for skin colour to return to normal

- * dry, burning, itching, or irritated eyes
- * dimness of vision
- * dry, itchy or scaly skin
- * acne or skin rash
- * stomach pain or discomfort
- * gastrointestinal disorders (nausea, i.e. feeling sick, vomiting, or diarrhoea)
- * mild abdominal pain
- * loss of appetite
- * weight loss
- * headache
- * tiredness
- * dizziness
- * depression
- * increased sensitivity of the skin when exposed to sunlight or the symptoms of sunburn (such as redness, itching, swelling, blistering) which may happen more quickly than normal
- * swollen glands in the neck, armpit or groin
- * signs of raised blood sugar levels, such as:
 - lethargy
 - thirst
 - passing large amounts of urine
 - blurred vision

Tell your doctor if you notice anything else that is making you unwell.

Other side effects not listed above may happen in some people.

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

After taking Lamprene

Storage

Keep your medicine in the original container until it is time to take it.

Store the capsules in a cool dry place where the temperature stays below 25 degrees C.

Do not store Lamprene or any other medicine in the bathroom, near a sink, or on a window sill.

This medicine will keep well if it is stored cool and dry.

Do not store this medicine in the car.

Heat and dampness can destroy some medicines.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or if the expiry date has passed, ask your pharmacist what to do with any capsules you have left over.

Product description

What it looks like

Lamprene soft gelatin capsules are plain, round, brown capsules with no markings.

The colour of the capsules may appear irregular or mottled. This is because the active ingredient consists of reddish-brown particles suspended in a dark brown oil-wax base.

Lamprene is available in containers of 100 capsules.

Ingredients

Active ingredient:

Lamprene capsules contain 50 mg of clofazimine as the active ingredient.

Inactive ingredients:

Lamprene capsules also contain:

- * acetanisole
- * butylated hydroxytoluene (E 320)
- * citric acid (E 330)
- * propylene glycol (E 1520)
- * rapeseed oil
- * lecithin (E 322)
- * wax blend composed of beeswax (E 901) and vegetable oils
- * sodium ethylparaben (E 215)
- * sodium propylparaben (E 217)
- * ethyl vanillin
- * gelatin
- * glycerin (E 422)
- * iron oxide black CI77499 (E 172)
- * iron oxide red CI77491 (E 172)

Sponsor

Lamprene is supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1 800 671 203

(R)= Registered Trademark

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