

Lamprene(R)

clofazimine

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.

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). It is always used in combination with two other medicines, dapsone and rifampicin. This helps to prevent the bacteria that causes leprosy (called *Mycobacterium leprae* or Hansen's bacillus) from developing resistance to the treatment.

Lamprene belongs to a group of medicines called antibacterials, which stop the growth of bacteria in the body.

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 have ever had an allergic reaction to clofazimine (the active ingredient) or to 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.

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 are pregnant or intend to become pregnant.

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

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

- * liver or kidney problems
- * frequent abdominal pain or diarrhoea

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

Tell your doctor if you are taking any other medicines, including any 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.

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.

How to take it

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

How long to take it

It is very important to keep taking Lamprene for as long as your doctor recommends, which may be for as long as two years.

In order for 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 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.

Symptoms of an overdose may include dizziness, headache, nausea (feeling sick), vomiting, stomach pains, diarrhoea, reduction in amount of urine passed, discolouration of the skin and urine.

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 you 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 (see Side Effects section).

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lamprene.

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

Things you must not do

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.

This medicine can cause headache, tiredness and dimness of vision in some people. Make sure you know how it affects you before you drive a car, operate machinery, or do anything else that could be dangerous.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp.

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 does appear to be burning, tell your doctor.

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.

All medicines can have side effects. 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.

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

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

- * severe pains in the stomach or abdomen
- * persistent diarrhoea or vomiting
- * vomiting blood or material that looks like coffee grounds
- * bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

The above are rare but serious side effects that need immediate medical attention.

Tell your doctor 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. Sweat, tears, saliva, semen, breast milk, urine and bowel motions may also be discoloured. 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 irritated eyes
- * dimness of vision
- * dry, itchy or scaly skin
- * acne or skin rash
- * nausea (feeling sick) or vomiting
- * mild abdominal pain
- * diarrhoea
- * loss of appetite
- * weight loss
- * headache or fever
- * tiredness
- * dizziness
- * depression
- * 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.

After taking Lamprene

Storage

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

- * Do not store your medicine in the bathroom or near a sink.
- * Do not leave it in the car or on window sills.

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 it has passed its expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What it looks like

Lamprene capsules are round, brown soft gelatin capsules with no markings; available in containers of 100 capsules.

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.

Ingredients

Lamprene capsules contain 50 mg of clofazimine as the active ingredient. They also contain the following inactive ingredients:

- * acetanisole
- * butylated hydroxytoluene
- * citric acid
- * propylene glycol
- * rapeseed oil
- * lecithin
- * wax blend composed of beeswax and vegetable oils
- * sodium ethylparaben
- * sodium propylparaben
- * ethyl vanillin
- * gelatin

- * glycerin
- * iron oxide black CI77499
- * iron oxide red CI77491

Sponsor

Lamprene is supplied in Australia by:

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

(R) = Registered Trademark

This leaflet was prepared in October 2005

(Imp191005c.doc) based on PI
(Imp191005i.doc)

Australian Registration Number.
Lamprene 50 mg AUST R 11116