

Lamogine(R)

dispersible/chewable tablets

contains the active ingredient lamotrigine

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about LAMOGINE tablets. It does not contain all of 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 taking LAMOGINE tablets against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What LAMOGINE is used for

LAMOGINE tablets are used for the treatment of epilepsy in adults and children aged 2 years and older.

Lamotrigine (the active ingredient in LAMOGINE tablets) belongs to a group of medicines called "anti-epileptic drugs".

Usually LAMOGINE tablets are initially used in addition to other medicines for the treatment of epilepsy. LAMOGINE is used in partial or generalised seizures including Lennox-Gastaut Syndrome.

It is thought that LAMOGINE tablets work by changing the levels of some chemicals associated with seizures.

Ask your doctor if you have any questions about why LAMOGINE tablets have been prescribed for you.

Your doctor may have prescribed LAMOGINE tablets for another reason.

LAMOGINE tablets are not addictive.

Before you take LAMOGINE

When you must not take it

Do not take LAMOGINE if you have an allergy to lamotrigine or any of the ingredients listed at the end of this leaflet. (See "Ingredients").

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 this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

- * you are allergic to foods, dyes, preservatives or any other medicines
- * you have a history of allergy or rash to other antiepileptic drugs
- * you are suffering, or have ever suffered, from any liver or kidney disorders
- * you have Parkinson's disease
- * you are pregnant or trying to become pregnant.

LAMOGINE may affect your unborn baby if you take it during pregnancy but it is still important that you control your fits while you are pregnant. Your doctor will discuss the risks and benefits of taking LAMOGINE during pregnancy and help you decide whether or not you should take LAMOGINE.

It is recommended that women on antiepileptic drugs receive pre-pregnancy counselling with regard to the risk on their unborn child.

Studies have shown a decrease in the levels of folic acid during pregnancy with LAMOGINE. It is therefore recommended that you take a folate supplement, e.g. 5mg folate daily, before becoming pregnant and during the first 12 weeks of your pregnancy.

- * you are breastfeeding.
LAMOGINE is thought to pass into breast milk.
Your doctor will discuss the risks and benefits of taking LAMOGINE tablets if you are breastfeeding.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LAMOGINE may interfere with each other. These include:

- * sodium valproate (Epilim, Valpro), a medicine used to treat epilepsy or mania
- * other antiepileptic medicines, such as carbamazepine, phenytoin, primidone and phenobarbitone
- * the antibiotic rifampicin
- * lopinavir and ritonavir, medicines used to treat HIV infection
- * any form of hormonal contraceptive (e.g. birth control pill) or hormonal replacement therapy (HRT).

These medicines may be affected by LAMOGINE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take LAMOGINE

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

They may differ from the information contained in this leaflet.

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

Using LAMOGINE for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with LAMOGINE tablets. During this period you may also notice that you have slight problems with your vision. As your reactions may be slower during this period you should not operate any machinery or appliances and you should not drive a car. If any of these effects do not go away or are troublesome you should see your doctor.

If you develop any skin rash (e.g. spots or 'hives') during LAMOGINE treatment contact your doctor immediately.

There are reports of skin rash associated with LAMOGINE treatment. Some of these may be serious and cause severe illness.

If you have any questions about taking LAMOGINE tablets ask your doctor or pharmacist.

How much to take

Take LAMOGINE tablets as directed by your doctor or pharmacist. Never change the dose yourself. Do not increase the dose more quickly than you have been told.

Your doctor and pharmacist will be able to tell you:

- * how many tablets to take at each dose
- * how many doses to take each day
- * when to take each of your doses.

The label on the container that the tablets were supplied in will give the same information. If there is something that you do not understand ask either your doctor or pharmacist.

It is usual for the dose of LAMOGINE tablets to start at quite a low level and be slowly increased

during the first few weeks of treatment. The doses that your doctor prescribes will generally depend on any other anti-epileptic medications you are taking for the treatment of epilepsy and your response to LAMOGINE tablets.

Hormonal contraceptives (such as the birth control pill) and LAMOGINE tablets:

Most people need a higher maintenance dose of LAMOGINE when they take hormonal contraceptives, so if you are taking these, your doctor may increase your dose. Your doctor will usually decrease your dose once you stop taking hormonal contraceptives.

You should tell your doctor if there are any changes in your menstrual pattern, such as breakthrough bleeding.

Your doctor may need to change the dose of LAMOGINE during your pregnancy.

How to take it

LAMOGINE tablets may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet).

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Do not stop taking LAMOGINE tablets, or change the dose without first checking with your doctor.

Use in children

LAMOGINE is not recommended for treatment of epilepsy in children under 2 years of age.

Children's weight should be checked and the dose reviewed as weight changes occur.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too many LAMOGINE tablets, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If too many LAMOGINE tablets have been taken it is likely that the following symptoms will be experienced: nausea, vomiting, tiredness/drowsiness and problems with eyesight.

While you are taking LAMOGINE

Your doctor or pharmacist will be able to tell you whether there are any special instructions while you are taking LAMOGINE tablets.

Things you must do

If you develop any skin rash (e.g. spots or 'hives') during LAMOGINE treatment, contact your doctor immediately.

There are reports of skin rash associated with LAMOGINE treatment. Some of these may be serious and cause severe illness.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

LAMOGINE may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Patients and caregivers should be alert and monitor for these effects.

If you or someone you know is showing any of the following warning signs of suicide while taking LAMOGINE, contact your doctor or a mental health

professional right away or go to the nearest hospital for treatment:

- * thoughts or talk of death or suicide
- * thoughts or talk of self-harm or harm to others
- * any recent attempts of self-harm
- * increase in aggressive behaviour, irritability, or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Tell your doctor or pharmacist that you are taking LAMOGINE tablets if you are about to be started on any new medicines.

If you become pregnant while taking this medicine, tell your doctor immediately.

There may be an increased risk of babies developing a cleft lip or cleft palate if LAMOGINE is taken during the first few months of pregnancy.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

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

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Things you must not do

Do not stop taking LAMOGINE tablets just because you feel better.

If you stop taking LAMOGINE tablets suddenly your epilepsy may come back or become worse. This is known as "rebound seizures".

Your doctor will advise you if you need to stop taking LAMOGINE tablets and how.

If you are unsure whether you should stop taking LAMOGINE tablets talk to your doctor or pharmacist.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use LAMOGINE tablets to

treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how LAMOGINE tablets affect you.

As with other anticonvulsant medicines for the treatment of epilepsy, LAMOGINE may cause dizziness and drowsiness in some people, and affect alertness.

Make sure you know how you react to LAMOGINE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LAMOGINE.

Like other medicines, LAMOGINE tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

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

- * rash
- * dizziness/unsteadiness
- * headache
- * drowsiness

- * feeling sick (nausea)
- * vomiting
- * diarrhoea
- * feeling weak
- * double or blurred vision
- * tremor
- * trouble sleeping
- * confusion
- * irritability/aggression
- * agitation, confusion
- * increased activity in children
- * joint or back pain
- * movement problems such as tics, unsteadiness and jerkiness
- * menstrual disorders in female patients.

Tell your doctor as soon as possible if you notice any of the following:

- * tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- * frequent infections such as fever, severe chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal
- * yellow skin (jaundice)
- * hallucinations
- * "Lupus-like reactions" which may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * signs of an allergic reaction such as skin rash, itching or hives; shortness of breath, wheezing or trouble breathing; swelling of the face, lips, tongue or other parts of the body
- * rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; usually accompanied by fever, aching muscles and generally

feeling unwell

- * meningitis, which may present as fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking LAMOGINE

Storage

Keep LAMOGINE tablets where children cannot reach them.

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

Keep LAMOGINE tablets in the container that they were supplied in until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep LAMOGINE tablets in a cool dry place where the temperature stays below 30 degrees C. Protect from light.

Do not store LAMOGINE tablets or any other medicine in the bathroom or near a sink. Do not leave them on a window sill or in the car.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

LAMOGINE dispersible/chewable tablets come in 5 different strengths.

LAMOGINE dispersible/ chewable tablets 5 mg are white to off-white, elongated, biconvex tablets smelling of blackcurrant. They are marked "GSCL2" on one side and "5" on the other.

Lamogine dispersible/ chewable tablets 25 mg, 50 mg, 100 mg and 200 mg are white to off-white, unscored, elliptical tablets with many sides and smelling of blackcurrant. The 25 mg tablet is marked "GSCL5" on one side and "25" on the other, the 50 mg tablet is marked "GSCX7" on one side and "50" on the other, the 100 mg tablet is marked "GSCL7" on one side and "100" on the other, and the 200 mg tablet is marked "GSEC5" on one side and "200" on the other.

All strengths of LAMOGINE dispersible/ chewable tablets are available in packs of 56 tablets.

Ingredients

The active ingredient in LAMOGINE tablets is lamotrigine.

Each LAMOGINE tablet contains 5 mg (LAMOGINE tablets 5 mg), 25 mg (LAMOGINE tablets 25 mg), 50 mg (LAMOGINE tablets 50 mg), 100 mg (LAMOGINE tablets 100 mg) or 200 mg (LAMOGINE tablets 200 mg) of lamotrigine.

Each LAMOGINE dispersible/ chewable tablet also contains the following inactive ingredients:

- * calcium carbonate
- * hydroxypropylcellulose
- * aluminium magnesium silicate
- * sodium starch glycollate
- * povidone
- * saccharin sodium
- * magnesium stearate
- * blackcurrant flavour.

LAMOGINE tablets do not contain gluten or lactose.

Supplier

Your LAMOGINE tablets are supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

Australian registration numbers:

LAMOGINE Dispersible/Chewable Tablets 5 mg: AUST R 114255

LAMOGINE Dispersible/Chewable Tablets 25 mg: AUST R 114258

LAMOGINE Dispersible/Chewable Tablets 50 mg: AUST R 114259

LAMOGINE Dispersible/Chewable Tablets 100 mg: AUST R 114260

LAMOGINE Dispersible/Chewable Tablets 200 mg: AUST R 114261

This leaflet was prepared on:

27 April 2009.