

LAMOTRUST

(Dispersible Tablets)

Lamotrigine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take this medicine.

This leaflet answers some common questions about lamotrigine. 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. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking lamotrigine against the risks this medicine could 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 is Lamotrusted used for?

Lamotrusted is used for the treatment of epilepsy in adults and children.

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

Epilepsy: Usually lamotrigine is initially used in addition to other medicines for the treatment of epilepsy. Lamotrigine is used in partial or generalised seizures including Lennox-Gastaut Syndrome.

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

Your doctor may have prescribed lamotrigine for another reason.

Lamotrigine is not known to be addictive.

Before you take Lamotrusted

Do not take if:

- you have ever had an allergic reaction to lamotrigine(See "Side Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

You must 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 are taking any other medicines. This is particularly important for sodium valproate ("Epilim, "Valpro").

- you are taking any form of hormonal contraceptive (e.g. "the pill") or HRT, other anti-epileptic drugs (e.g. carbamazepine or phenobarbitone) or medicines you buy without a prescription.
- you have Parkinson's disease.
- you are breastfeeding, pregnant or trying to become pregnant.

Lamotrigine 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.

It is recommended that women on antiepileptic drugs, such as lamotrigine, receive pre-pregnancy counseling with regard to the risk on their unborn child.

There is not enough information available on the use of lamotrigine during pregnancy to determine whether or not it is safe.

Lamotrigine is thought to pass into breast milk.

Your doctor will discuss the risks and benefits of using lamotrigine if you are pregnant or breastfeeding, including the risk to mother and foetus of uncontrolled epilepsy, when deciding on treatment options.

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

How do I take this medicine?

Using lamotrigine for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with lamotrigine. 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 lamotrigine treatment contact your doctor immediately (See "While you are taking lamotrigine, Things you must do").

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

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

How much to take

Take lamotrigine 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 to start at quite a low dose level and then slowly increase during the first few weeks of treatment. The doses that your doctor prescribes will generally depend on any other antiepileptic medications you are taking for the treatment of epilepsy and your response to lamotrigine.

Hormonal contraceptives: If you start or stop taking hormonal contraceptives (e.g. "the pill") while taking lamotrigine your doctor may need to adjust the dose of lamotrigine depending on how well your condition is being treated.

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 lamotrigine during your pregnancy.

How to take it

Lamotrigine 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

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

Use in children

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

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre for advice, or go to Accident or Emergency department at your nearest hospital, if you think you or anyone else may have taken too many lamotrigine tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

In Australia call 13 11026 for Poisons Information Centers.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

If too many lamotrigine 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 lamotrigine

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

Things you must do

Lamotrigine may cause a serious skin rash that may cause you to be hospitalized or to stop lamotrigine; it may rarely cause death.

There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when you begin taking lamotrigine, within the first 2 to 8 weeks of treatment. But it can happen in people who have taken lamotrigine for any period of time. Children between 2 to 16 years of age have a higher chance of getting this serious skin reaction while taking lamotrigine.

The risk of getting a rash is higher if you:

- take lamotrigine while taking valproate (valproic acid)
- take a higher starting dose of lamotrigine than your healthcare provider prescribed
- increase your dose of lamotrigine faster than prescribed.

Lamotrigine can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions.

Call your healthcare provider right away if you have any of the following:

- a skin rash
- hives
- fever
- swollen lymph glands
- painful sores in the mouth or around your eyes
- swelling of your lips or tongue
- yellowing of your skin or eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections

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

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

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

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

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 lamotrigine just because you feel better.

Epilepsy: If you stop taking lamotrigine 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 lamotrigine and how.

If you are unsure whether you should stop taking lamotrigine 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 lamotrigine 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 lamotrigine affect you.

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

Make sure you know how you react to lamotrigine 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 lightheadedness 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.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking lamotrigine, even if the problem is not listed below.

Like other medicines, lamotrigine 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.

The most commonly reported side effects are:

- dizziness/unsteadiness
- rash
- headache
- drowsiness
- feeling sick, also called nausea
- vomiting
- feeling weak
- double vision, blurred vision
- tremor (shakiness)
- trouble sleeping
- loss of memory
- confusion
- irritability/aggression
- agitation
- increased activity in children
- joint or back pain

Other reported side effects include:

- diarrhoea
- liver problems
- tiredness or feeling sleepy
- movement problems such as tics, unsteadiness and jerkiness
- hallucinations.

Some people may have changes in their blood count, which may make them feel tired, short of breath and more susceptible to infections. They may also bleed or bruise very easily or have mouth ulcers or a sore throat.

In general these side effects usually happen only during the first few weeks of treatment with lamotrigine. If any of these side effects persist, or are troublesome, see your doctor.

Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. Information from a large number of studies in patients being treated with anti-epileptic medicines such as lamotrigine has shown a small number of reports of suicidal behaviour (including suicidal thoughts and suicide attempts).

Tell your doctor immediately if you experience any of the following:

- Suicide thoughts
- Suicide attempts

Tell your Doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

Tell your doctor immediately if you notice any of the following:

- **Suicidal thoughts**
- **Suicide attempts**
- Any skin reaction (e.g. rash or 'hives') (See "While you are taking lamotrigine, Things you must do").
- Swelling of the face, lips or tongue.
- Sore mouth or sore eyes.
- A high temperature (fever).
- Swollen glands.
- Drowsiness.
- Easy bruising or unusual bleeding.
- Yellow skin (jaundice).

If you are taking lamotrigine for epilepsy, rarely, you may start to experience more seizures than usual. Tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure.

These are all very serious side effects and you may need urgent medical attention or hospitalisation.

Serious side effects are rare.

Another rare side effect is "Lupus-like reactions" which may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health.

A very rare side effect is meningitis which may present as a group of symptoms consisting of fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord.

If you think you are having an allergic reaction to lamotrigine, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident or emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

Tell your doctor if you are female and your menstrual periods change.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

How do I store lamotrigine tablets?

Keep lamotrigine tablets where children cannot reach them such as in a locked cupboard.

Keep lamotrigine tablets in the container that they were supplied in until time to take them.

Store lamotrigine tablets below 25°C. Protect from light and moisture.

Do not leave in a car, on a window sill or in the bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

What Lamotrusted tablets look like

Lamotrusted dispersible tablets come in 4 different strengths.

- Lamotrusted tablets 25 mg are White to off white, round, flat face beveled edge tablets, plain on both sides. AUST R 150747
- Lamotrusted tablets 50 mg are White to off white, round, flat face beveled edge tablets, plain on both sides. AUST R 150748
- Lamotrusted tablets 100 mg are White to off white, round, flat face beveled edge tablets, plain on both sides. AUST R 150749
- Lamotrusted tablets 200 mg are White to off white, round, flat face beveled edge tablets, plain on both sides. AUST R 150750

Epilepsy:

All strengths of Lamotrusted tablets are available in packs of 56 tablets.

Ingredients

The active ingredient in Lamotrusted tablet is lamotrigine.

Each tablet contains 25 mg, 50 mg, 100 mg or 200 mg of lamotrigine.

Each tablet also contains:

- crospovidone,
- povidone K-30,
- mannitol,
- microcrystalline cellulose,
- colloidal anhydrous silica,
- aspartame,
- croscarmellose sodium,
- magnesium stearate and
- trusil blackcurrant flavour.

Lamotrusted tablets do not contain gluten or lactose.

Sponsor

Torrent Australasia Pty Ltd
100 George St,
Parramatta, NSW 2150
AUSTRALIA

Supplier

Meditech Int Pty Ltd

Unit 5/36 Campbell Av
Cromer NSW 2099

Lamotrusted is a trademark of the
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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.

This leaflet was amended in
November 2012.