

LAMICTAL

(dispersible/chewable) Tablets

Lamotrigine

New Zealand Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Lamictal tablets.

This leaflet answers some common questions about Lamictal 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. 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 Lamictal tablets 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 are Lamictal tablets used for?

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

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

Epilepsy: Usually Lamictal tablets are initially used in addition to other medicines for the treatment of epilepsy. Lamictal is used in partial

or generalised seizures including Lennox-Gastaut Syndrome.

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

Your doctor may have prescribed Lamictal tablets for another reason.

Lamictal tablets are not addictive.

Before you take Lamictal tablets

Do not take if:

You must not take Lamictal tablets if:

- you have ever had an allergic reaction to Lamictal tablets (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 have Parkinson's disease.

- you have ever developed meningitis after taking lamotrigine.
- you are taking any other medicines. This is particularly important for sodium valproate ("Epilim" or "Valpro").
- you are taking any form of hormonal contraceptive (e.g. "the pill", ethinylestradiol/levonorgestrel) or HRT.
- you are taking any other anti-epileptic drugs (e.g. carbamazepine, phenobarbitone, phenytoin or primidone).
- you are taking any medicines you buy without a prescription.
- you are taking rifampicin, which is used to treat infections, including tuberculosis.
- you are taking medicine which is used to treat Human Immunodeficiency Virus (HIV) infection (e.g. lopinavir/ritonavir or atazanavir/ritonavir).
- you are taking any other medicines containing lamotrigine.
- if you have a condition called Brugada syndrome (a genetic disease that affects the heart), or other heart problems.
- you have a serious immune system condition (haemophagocytic lymphohistiocytosis or HLH), in which the part of the body that fights disease is overactive.

- **you are taking dofetilide, a medicine used to treat heart problems.**

Tell your doctor if you are taking risperidone, a medicine used to treat bipolar disorder. You may be more likely to feel sleepy or drowsy when you take risperidone and lamotrigine together.

- **you are, pregnant or trying to become pregnant.**

Lamictal 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 Lamictal during pregnancy and help you decide whether or not you should take Lamictal.

It is recommended that women on antiepileptic drugs, such as Lamictal, 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 Lamictal. 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.

- **you are breastfeeding.**

Lamictal is thought to pass into breast milk.

Your doctor will discuss the risks and benefits of using Lamictal tablets if you are breastfeeding.

How do I take Lamictal tablets?

Using LAMICTAL Tablets for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with Lamictal 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 Lamictal treatment contact your doctor immediately.

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

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

How much to take

Take Lamictal 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 Lamictal 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 Lamictal tablets.

Hormonal contraceptives (such as the birth control pill) and Lamictal tablets: Most people need a higher maintenance dose of Lamictal tablets 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 Lamictal during your pregnancy.

How to take it

Lamictal tablets may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet). Never take only part of the liquid.

How long to take it for

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

Use in children

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

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 Lamictal tablets, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

In New Zealand call 0800 POISON (0800 764 766).

Keep telephone numbers for these places handy.

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

If too many Lamictal tablets have been taken, you may be more likely to experience the following serious side effects which may be fatal: nausea, vomiting, tiredness/drowsiness and problems with eyesight, rapid or uncontrollable eye movements, twitching, impaired consciousness, clumsiness or lack of coordination, unsteadiness, convulsions, changes in your heart beat and coma.

While you are taking Lamictal tablets

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

Things you must do

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

There are reports of serious skin rash with Lamictal that may need hospital treatment or drug withdrawal; rarely serious skin rash may cause death.

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

Lamictal may interfere with some laboratory tests to detect other drugs. If you require a laboratory test, tell your doctor or hospital that you are taking Lamictal.

Pregnancy and breastfeeding

Talk to your doctor as soon as possible if you are pregnant, or if you are planning to become pregnant. There may be an increased risk of babies developing a cleft lip or cleft palate if Lamictal tablets is taken during the first few months of pregnancy.

Talk to your doctor if you're breast feeding or planning to breast feed. The active ingredient of Lamictal passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding while you're taking Lamictal.

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 Lamictal tablets just because you feel better.

Epilepsy: If you stop taking Lamictal 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 Lamictal tablets and how.

If you are unsure whether you should stop taking Lamictal 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 Lamictal 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 Lamictal tablets affect you.

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

Make sure you know how you react to Lamictal 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.

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 Lamictal tablets, even if the problem is not listed below.

Like other medicines, Lamictal 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.

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
- nightmares
- unusual hair loss or thinning (alopecia)
- a decrease in antibodies (immunoglobulins)

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 Lamictal. 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 Lamictal 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:

- Suicidal 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:

- Any skin reaction (e.g. rash or 'hives').
- 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 Lamictal 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 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.

A serious immune system condition, in which the part of the body system that fights disease is overactive, has been reported while taking Lamictal. Although, it has been reported very rarely, it can be life-threatening, so it is important that you know the symptoms to look out for. Symptoms include:

- a high temperature (fever).
- skin rashes
- trouble walking or seeing, and fits (seizures) for the first time or happening more often
- enlarged liver and/or spleen with pain and/or tenderness in the region towards the top of the stomach
- yellowing of the skin and/or eyes
- swollen glands in the neck, armpit and/or groin
- bleeding and/or bruising more easily; looking pale, feeling tired.

In most cases these symptoms may be signs of less serious side effects, but you must be aware that they can be signs of a condition which can be serious if not recognised early.

If you think you are having an allergic reaction to Lamictal tablets, 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 Lamictal tablets?

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

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

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

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 Lamictal tablets look like

Lamictal dispersible/chewable tablets come in 5 different strengths.

Lamictal dispersible/ chewable tablets 2 mg are white to off-white round tablets, with an odour of blackcurrant. They are marked "LTG 2" on one side and engraved with two overlapping super-ellipses on the other.

Lamictal dispersible/ chewable tablets 5 mg are white to off-white, long, convex tablets, unscored, smelling of blackcurrant. They are marked "GS CL 2" on one side and "5" on the other.

Lamictal dispersible/chewable tablets 25 mg, 50 mg and 100 mg are white to off-white, multi-faceted, superelliptical (rounded square), unscored tablets and smelling of blackcurrant. The tablets may be slightly mottled.

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.

Epilepsy:

25 mg, 50 mg and 100 mg tablets are available in packs of 56 tablets. 2 mg and 5 mg tablets are available in packs of 30 tablets.

Not all strengths or pack sizes may be marketed in New Zealand.

Ingredients

The active ingredient in Lamictal tablets is lamotrigine. Each Lamictal tablet contains 2 mg (Lamictal tablets 2 mg), 5 mg (Lamictal tablets 5 mg), 25 mg (Lamictal tablets 25 mg), 50 mg (Lamictal tablets 50 mg) or 100 mg (Lamictal tablets 100 mg) of lamotrigine.

Each Lamictal dispersible/ chewable tablet also contains:

- calcium carbonate, hydroxypropyl cellulose, aluminium magnesium silicate, sodium starch glycolate, povidone, saccharin sodium, magnesium stearate and blackcurrant flavour.

Lamictal tablets do not contain gluten.

Lamictal tablets do not contain lactose.

Sponsor

Lamictal tablets are marketed in New Zealand by:

GlaxoSmithKline NZ Limited, Auckland, New Zealand

FREEPHONE: 0800 808 500

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.

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The information provided applies only to Lamictal tablets.

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