

LAMICTAL

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LAMICTAL?

LAMICTAL contains the active ingredient lamotrigine. LAMICTAL tablets are used to treat epilepsy in adults and children aged 2 years and over.

For more information, see Section [1. Why am I using LAMICTAL?](#) in the full CMI.

2. What should I know before I use LAMICTAL?

Do not use if you have ever had an allergic reaction to LAMICTAL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LAMICTAL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LAMICTAL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LAMICTAL?

- 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 and your response to LAMICTAL tablets.

More instructions can be found in Section [4. How do I use LAMICTAL?](#) in the full CMI.

5. What should I know while using LAMICTAL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using LAMICTAL.• Tell your doctor immediately if you become pregnant or intend to become pregnant whilst using LAMICTAL.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor.• Do not use LAMICTAL tablets to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how LAMICTAL affects you.
Drinking alcohol	<ul style="list-style-type: none">• If you are drinking alcohol while using the medicine dizziness or light headedness may be worse.• Children should not ride a bike or climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place below 30°C. Protect from light.

For more information, see Section [5. What should I know while using LAMICTAL?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported to be less serious include headache, dizziness, vomiting, pain in back and joints, skin rash, tiredness and liver problems. Tell your doctor immediately if you have any thoughts of harming yourself or committing suicide.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LAMICTAL

Active ingredient: Lamotrigine

Consumer Medicine Information (CMI)

This leaflet provides important information about using LAMICTAL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LAMICTAL.**

Where to find information in this leaflet:

- [1. Why am I using LAMICTAL?](#)
- [2. What should I know before I use LAMICTAL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LAMICTAL?](#)
- [5. What should I know while using LAMICTAL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using LAMICTAL

LAMICTAL contains the active ingredient Lamotrigine.

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.

2. What should I know before I use LAMICTAL?

Warnings

Do not use LAMICTAL if:

- you have ever had an allergic reaction to LAMICTAL tablets (See "[6. Are there any side effects?](#)") or any of the ingredients listed toward the end of this leaflet. (See "[Product details](#)").
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines.
- have a history of allergy or rash to other antiepileptic drugs.
- are suffering, or have ever suffered, from any liver or kidney disorders.

- have Parkinson's disease.
- have ever developed meningitis after taking lamotrigine.
- have a condition called Brugada syndrome (a genetic disease that affects the heart), or other heart problems.
- have a serious immune system condition (haemophagocytic lymphohistiocytosis or HLH), in which the part of the body that fights disease is overactive.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Check with your doctor if you are pregnant or intend to become pregnant.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

LAMICTAL is thought to pass into breast milk.

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

3. What if I am taking other medicines?

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

Some medicines which are similar to LAMICTAL should not be used together as an overdose may result.

Some medicines may affect how LAMICTAL works, or make it more likely that you'll have side effects. These include:

- sodium valproate ("Epilim" or "Valpro").
- oestrogen-containing products, including hormonal contraceptive (e.g. "the pill", ethinylestradiol/levonorgestrel) or hormone replacement therapy (HRT).

- any other anti-epileptic drugs (e.g. carbamazepine, phenobarbitone, phenytoin or primidone).
- any medicines you buy without a prescription.
- rifampicin, which is used to treat infections, including tuberculosis.
- medicine which is used to treat Human Immunodeficiency Virus (HIV) infection (e.g. lopinavir/ritonavir or atazanavir/ritonavir).
- dofetilide, a medicine used to treat heart problems.
- 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.
- any other medicines containing lamotrigine.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LAMICTAL.

4. How do I use LAMICTAL?

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.

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.

Children

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

Epilepsy:

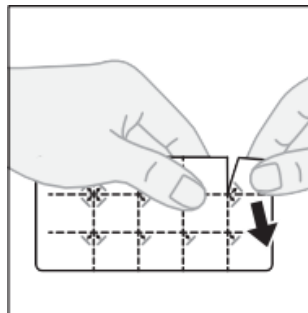
Children's weight should be checked, and the dose reviewed as weight changes occur.

How to take LAMICTAL

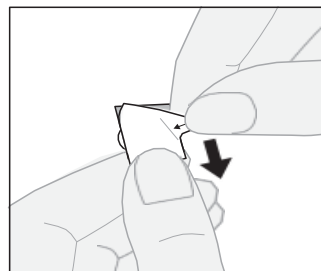
LAMICTAL tablets may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet). Never take only part of the liquid.

The 25 mg, 50 mg, 100 mg and 200 mg chewable/dispersible tablets may come in special packaging to prevent children removing them. Instructions for opening this packaging are given below.

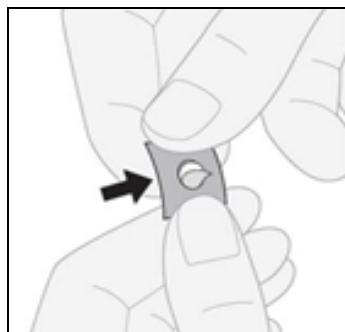
1. Separate one tablet: tear along the cutting lines to separate one "pocket" from the blister.



2. Peel back the outer layer: starting at the corner, lift and peel over the pocket.



3. Push out the tablet: gently push one end of the tablet through the foil layer.



If you forget to use LAMICTAL

LAMICTAL should be used regularly at the same time each day as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

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

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

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

If you use too much LAMICTAL

If you think that you have used too much LAMICTAL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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 heartbeat and coma.

5. What should I know while using LAMICTAL?

Things you should do

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

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.

Call your doctor straight away 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.
- are 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.
- for any reason, you have not taken your medicine exactly as directed.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using LAMICTAL.

Things you should not do

- stop taking LAMICTAL tablets just because you feel better.

- stop using this medicine suddenly or lower the dosage without checking with your doctor.
- take LAMICTAL to treat any other complaints unless your doctor tells you to.
- give your medicine to anyone else, even if they have the same condition as you.

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LAMICTAL affects 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

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.

Keep it where young children cannot reach it.

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

When to discard your medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Nervous system disorders:</p> <ul style="list-style-type: none"> dizziness/unsteadiness movement problems such as tics, unsteadiness and jerkiness drowsiness trouble sleeping tremor (shakiness) increased activity in children <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> diarrhea feeling sick, also called nausea vomiting <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> hallucinations nightmares loss of memory confusion irritability/aggression agitation <p>Skin and subcutaneous disorders:</p> <ul style="list-style-type: none"> rash unusual hair loss or thinning (alopecia) <p>Eye disorders:</p> <ul style="list-style-type: none"> double vision, blurred vision <p>General disorders:</p> <ul style="list-style-type: none"> tiredness or feeling sleepy joint or back pain feeling weak runny nose headache <p>Immune system disorders:</p> <ul style="list-style-type: none"> a decrease in antibodies (immunoglobulins) changes in blood count which may make them feel tired, short 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> of breath and more susceptible to infections bleed or bruise very easily or have mouth ulcers or a sore throat. <p>Hepatobiliary disorders:</p> <ul style="list-style-type: none"> liver problems trouble sleeping 	
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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.

Serious side effects

Serious side effects	What to do
<p>Psychotic disorders:</p> <ul style="list-style-type: none"> suicidal thoughts suicide attempts <p>Allergic reactions:</p> <ul style="list-style-type: none"> wheezing swelling of the face, lips or tongue hayfever fainting sore mouth or sore eyes swollen glands <p>Skin and subcutaneous disorders:</p> <ul style="list-style-type: none"> rash or hives red nodules or patches on the skin (pseudolymphoma) erythema multiforme easy bruising or unusual bleeding yellow skin (jaundice) <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> "lupus like reactions" which may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health <p>Nervous system disorders:</p> <ul style="list-style-type: none"> increase in seizure frequency 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 	<p>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.</p> <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure.</p>

Serious side effects	What to do
<p>Immune system disorders: 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:</p> <ul style="list-style-type: none"> • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>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.</p>

Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://pophealth.my.site.com/carmreportnz/s/>.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LAMICTAL contains

Active ingredient (main ingredient)	Lamotrigine (2, 5, 25, 50 or 100) mg. The amount depends on which strength of LAMICTAL you have been given.
Other ingredients (inactive ingredients)	calcium carbonate, hydroxypropyl cellulose, aluminium magnesium silicate, sodium starch glycollate, povidone, saccharin sodium,

	magnesium stearate and blackcurrant flavour.
Potential allergens	none

LAMICTAL tablets do not contain gluten.

LAMICTAL tablets do not contain lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What LAMICTAL looks like

LAMICTAL is dispersible/chewable tablets comes in 5 different strengths.

LAMICTAL chewable/dispersible tablet 2 mg	TT50 – 4887/1e
LAMICTAL chewable/dispersible tablet 5 mg	TT50 – 4887/1a
LAMICTAL chewable/dispersible tablet 25 mg	TT50 – 4887/1
LAMICTAL chewable/dispersible tablet 50 mg	TT50 – 4887/1b
LAMICTAL chewable/dispersible tablet 100 mg	TT50 – 4887/1c

LAMICTAL dispersible/ chewable tablets 2 mg (TT50-4887/1e) are white to off-white round tablets, smelling 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 (TT50-4887/1a) 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 (TT50-4887/1), 50 mg (TT50-4887/1b) and 100 mg (TT50-4887/1c) 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.

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.

Who distributes LAMICTAL

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown

Auckland 1143
New Zealand

Phone: (09) 367 2900

Facsimile: (09) 367 2910

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