

LAMICTAL TABLET/DISPERSIBLE TABLET

Lamotrigine (50mg, 100mg, 5mg, 25mg)

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What LAMICTAL is used for
Lamictal can be used in two different conditions: Epilepsy and Bipolar disorder (manic depression). **Ask your doctor if you have any questions about why Lamictal has been prescribed for you.** Your doctor may have prescribed it for another reason.

How LAMICTAL works

Epilepsy: Lamictal is used to treat or prevent various types of epilepsy in adults and children. Lamictal may be used on its own to treat adults and children over 12 years. Lamictal can also be used in combination with other anti-epileptic medicines in both adults and children aged 2 years and over. Sometimes other anti-epileptic medicines may be stopped after Lamictal has been started.

Bipolar Disorder: Lamictal is also used to help prevent depression in adults over 18 years of age with bipolar disorder. Lamictal should not be used to treat bipolar disorder in children (under 18 years of age).

Before you use LAMICTAL

- When you must not use it

Do not take or use Lamictal if you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of Lamictal Tablets.

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

- Before you start to use it

Talk to your doctor or pharmacist before taking Lamictal:

- If you have any kidney problems
- If you have ever developed a rash after taking lamotrigine or other medicines for bipolar disorder or epilepsy
- If you have ever developed meningitis (swelling of the membranes of the brain and spinal cord) after taking lamotrigine
- If you are already taking medicine that contains lamotrigine
- If you have intolerance to a type of sugar called lactose
- If you have a condition called **Brugada syndrome** (a genetic disease that affects the heart), or other heart problems.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including herbal medicines or other medicines bought without a prescription.

Some medicines interact with Lamictal. These include:

- Valproate, used to treat epilepsy and mental health problems

- Carbamazepine, used to treat epilepsy and mental health problems
- Phenytoin, primidone or phenobarbitone, used to treat epilepsy
- Risperidone, used to treat mental health problems
- Rifampicin, which is an antibiotic
- Medicines used to treat Human Immunodeficiency Virus (HIV) infection (a combination of lopinavir and ritonavir or atazanavir and ritonavir)
- Oestrogen-containing products, including hormonal contraceptives (such as “the pill”) and hormone replacement therapy (HRT)

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

How to use LAMICTAL

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It may take a while to find the best dose of Lamictal for you. The dose you take will depend on:

- Your age
- Whether you are taking Lamictal with other medicines
- Whether you have any kidney or liver problems

Your doctor will prescribe a low dose to start and gradually increase the dose over a few weeks until you

reach a dose that works for you (called the effective dose). Never take more Lamictal than your doctor tells you to.

How to take/use Lamictal tablets

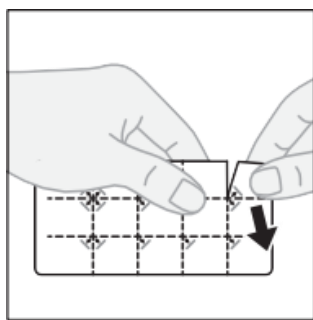
Swallow Lamictal tablets whole. Do not chew or crush them.

How to take/use Lamictal dispersible tablets

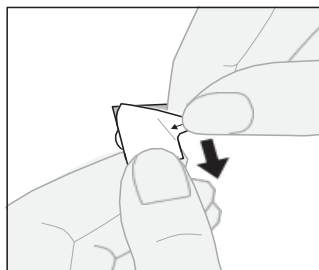
- A tablet can be swallowed whole with a little water or can be dissolved in water to make a liquid medicine. Never take only partially of the liquid.
- To make a liquid medicine, add the tablet to a little water, in a glass. Use enough water to cover the whole tablet. Leave for about a minute, until the tablet has fully dissolved, and then drink all of the liquid. Add a little more water to the glass and drink this to make sure all of the medicine has been taken.
- Do not try to take half a tablet or give half a tablet to your child.

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

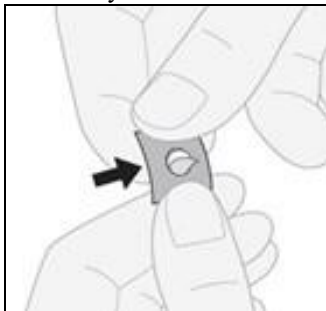
1. **Separate one tablet:** tear along the cutting lines to separate one "pocket" from the blister.



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.



When to use it

The label on your pack should tell you how many tablets to take and how often to take them. If the label doesn't say, or if you are not sure, ask your doctor or pharmacist.

- How long to use it

Do not stop taking Lamictal suddenly unless instructed by your doctor because your epilepsy may come back or become worse.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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

- If you use too much (overdose)

If you take too much Lamictal, or if someone else takes your medicine by mistake, contact your doctor or nearest casualty department immediately.

Symptoms of overdose:

- Involuntary eye movements
- Lack of coordination in movements
- Reduced consciousness level
- Convulsion
- Coma
- Intraventricular conduction delay

While you are using it

- Things you must do

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 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 breast feeding while you're taking Lamictal.

If you are taking hormonal contraceptives e.g. "the pill" and you notice any changes in your menstrual periods (such as breakthrough bleeding or spotting), tell your doctor as soon as possible as this may be a sign that Lamictal is having an effect on how your contraceptive is working.

Contact your doctor immediately if you develop any skin rash such as spots or 'hives' during Lamictal treatment.

There are reports of severe, potentially life-threatening rashes associated with Lamictal treatment, particularly in children. Lamictal should be discontinued at the first sign of rash unless the rash is clearly not drug related.

The risk of serious skin reactions may be associated

with a variant in genes called HLA B*1502 in people from Asian origin (mainly Han Chinese and Thai). If you have been tested previously and know you are carrying this genetic variant, discuss this with your doctor before taking Lamictal.

Serious immune system condition (Haemophagocytic lymphohistiocytosis or HLH)

A serious immune system condition, in which the part of the body that fights disease is overactive, has been reported while taking Lamictal. Although it has been reported very rarely (up to 1 in 10,000 people), it can be life-threatening.

Contact your doctor immediately if you have any of the associated symptoms.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Do not increase your dose of Lamictal tablets or take more frequent doses than those prescribed by your doctor.

- Things to be careful of

Be careful driving or operating machinery until you know how Lamictal affects you. 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. Children should not ride a bike,

climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.

Kidney or liver problems: If you or your child have kidney or liver problems your doctor may prescribe a lower dose, depending on how severe the kidney or liver problem is.

Side Effects Like all medicines, Lamictal can have side effects. If you feel that Lamictal is not making you feel better or you start to feel worse, seek your doctor's advice at once. Most people taking this medicine find it causes no problems. If any of the following symptoms occur, it is important to tell your doctor immediately, as more serious problems can happen if they are left ignored:

- Skin rashes or redness, which may develop into severe skin reactions including red spots or patches that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (*Erythema multiforme*), widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens Johnson syndrome* and *toxic epidermal necrolysis*)
- Increased sensitivity of the skin to sunlight (*photosensitivity reaction*)
- A sore mouth or eyes
- Swelling around the face
- If you get a high temperature, 'flu-like' symptoms or swollen glands
- If you start feeling very tired, if you get any unexpected bruising or bleeding, or if you start getting more infections (e.g. colds) than usual, or if you develop a sore throat.

Haemophagocytic lymphohistiocytosis

(HLH)

There have been reports of a rare but very serious immune system reaction, in patients taking lamotrigine.

Contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking lamotrigine: fever, rash, neurological symptoms (e.g. shaking or tremor, confusional state).

If you have any of the associated symptoms, immediately report them to your doctor. 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.
- Contact your doctor immediately** if you have any of these symptoms.

There have been rare reports of liver problems while taking Lamictal tablets. If you have one or more of the following symptoms, which may or may not be accompanied by feeling sick and generally unwell, tell your doctor immediately:

- Yellowing of the skin

- Itching
- Abdominal pain and/or tenderness. Tell your doctor as soon as possible if you notice any of the following:
- Blurred vision, double vision, redness of the eye (conjunctivitis), dizziness, headache, tiredness or feeling sleepy, difficulty sleeping, feeling or being sick, diarrhoea, hallucinations, back or joint pain

- which sometimes may be accompanied by fever and/or general ill health (lupus), feeling irritable, aggressive, agitated, confused, or having nightmares
- red nodules or patches on the skin (pseudolymphoma)
 - Unsteadiness or loss of co-ordination when you walk
 - If you have Parkinson's disease, any worsening of your symptoms such as shaking of the arms or legs, rolling of the eyes or a chewing movement of the mouth
 - inflammation of the kidney, which may occur in association with inflammation of the eye
 - Unusual movements that you cannot control such as jerking or shaking of the arms or legs, or rapideye movements.
 - A group of symptoms together including: - 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 (meningitis).

Tell your doctor immediately or go to the nearest hospital if you have any thoughts of harming yourself or committing suicide while taking Lamictal. If you are taking Lamictal to prevent extreme mood swings, you may not experience the full effect for several weeks. Occasionally, the symptoms of depression or bipolar disorder may include thoughts of harming yourself or committing suicide. Contact your doctor if you experience any worsening of your condition or develop other new symptoms at any time during your treatment. 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. Tell your doctor or pharmacist if you notice any other side effects from your medicine, which are not mentioned here.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)))

Storage and Disposal of LAMICTAL

- Storage

Keep your tablets out of the reach and sight of children. Lamictal Tablet (50mg, 100mg): Store below 30°C. Lamictal Dispersible Tablet (5mg, 25mg): Store below 30°C.

Do not use after the expiry date stated on the label. If your doctor tells you to stop taking the tablets, please return any left over to your pharmacist. Only keep them if instructed to do so by your doctor.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Lamictal Tablet (50mg, 100mg): Pale yellowish brown, multifaceted, superelliptical unscored tablet.

50mg: Branded 'GSEE1' on one side, with '50' on the reverse. 100mg: Branded 'GSEE5' on one side, with '100' on the reverse. *Lamictal Dispersible Tablet (5mg, 25mg):*

White to off-white tablet with odour of blackcurrant. The tablets may be slightly mottled. 5mg: Elongated, biconvex unscored tablet, branded 'GSCL2' on one side and '5' on the other. 25mg: Multi-faceted, superelliptical, unscored tablet, branded 'GSCL5' on one side and '25' on the other.

Available in blisters of 30's.

- Ingredients

Active ingredient(s)
Lamictal contains lamotrigine

Inactive ingredient(s)
Tablets:
Lactose
Microcrystalline cellulose
Povidone
Sodium starch glycolate
Iron oxide yellow (E172)
Magnesium stearate.

Dispersible Tablets:
Calcium carbonate Low substituted hydroxypropyl cellulose
Aluminium magnesium silicate
Sodium starch glycolate
Povidone
Saccharin sodium
Blackcurrant flavor
Magnesium stearate

- MAL number

Lamictal Tablet 50mg
MAL19930433ACRZ

Lamictal Tablet 100mg
MAL19930435ACRZ

Lamictal Dispersible Tablet 5mg
MAL19970261ACRZ

Lamictal Dispersible Tablet 25mg
MAL19970262ACRZ

Manufacturer

Delpharm Poznań
Spółka Akcyjna ul.
Grunwaldzka 189
60-322 Poznań
Poland

Product Registration

Holder

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Malaysia

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