

Package leaflet: Information for the User

Lamictal® 100 mg chewable/dispersible tablets
lamotrigine

- Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- * Keep this leaflet. You may need to read it again.
 - * If you have any further questions, ask your doctor or pharmacist.
 - * This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
 - * If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 What Lamictal is and what it is used for
- 2 What you need to know before you take Lamictal
- 3 How to take Lamictal
- 4 Possible side effects
- 5 How to store Lamictal
- 6 Contents of the pack and other information

1 What Lamictal is and what it is used for

Lamictal belongs to a group of medicines called *anti-epileptics*. It is used to treat two conditions — **epilepsy** and **bipolar disorder**.
Lamictal treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).

- For adults and children aged 13 years and over, Lamictal can be used on its own or with other medicines, to treat epilepsy. Lamictal can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.
- For children aged between 2 and 12 years, Lamictal can be used with other medicines, to treat those conditions. It can be used on its own to treat a type of epilepsy called typical absence seizures.

Lamictal also treats bipolar disorder.
People with bipolar disorder (sometimes called *manic depression*) have extreme mood swings, with periods of mania (excitement or euphoria) alternating with periods of depression (deep sadness or despair). For adults aged 18 years and over, Lamictal can be used on its own or with other medicines, to prevent the periods of depression that occur in bipolar disorder. It is not yet known how Lamictal works in the brain to have this effect.

2 What you need to know before you take Lamictal

Do not take Lamictal:

- * **if you are allergic** (*hypersensitive*) to lamotrigine or any of the other ingredients of this medicine (listed in Section 6).

If this applies to you:
➡ **Tell your doctor**, and don't take Lamictal.

Warnings and precautions

Take special care with Lamictal
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

What Lamictal chewable/dispersible tablets look like and contents of the pack
Lamictal 100 mg chewable/dispersible tablets are white to off-white multi-faceted, super-elliptical, tablets with a blackcurrant odour, marked "GSCL7" on one side and "100" on the other. The tablets may be slightly mottled and they come in blister packs of 56 chewable/dispersible tablets.

Parallel Product Authorisation Holder:
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Repackaged by:
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Lamictal is a registered trademark of GlaxoSmithKline Group of Companies.

PPA23176/003/005

Revision date: 23/05/2022

Blind or partially sighted?
Is this leaflet hard to see or read?

Phone Lexon Pharmaceuticals (Ireland) Limited,
Tel: +35318710550 for help.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Lamictal	Belgium	Lamictal	Bulgaria	Lamictal
Croatia	Lamictal	Cyprus	Lamictal	Czech Republic	Lamictal
Denmark	Lamictal	Estonia	Lamictal	Finland	Lamictal
France	Lamictal	Germany	Lamictal	Greece	Lamictal
Hungary	Lamictal	Iceland	Lamictal	Ireland	Lamictal
Italy	Lamictal	Latvia	Lamictal	Lithuania	Lamictal
Luxemburg	Lamictal	Malta	Lamictal	The Netherlands	Lamictal
Norway	Lamictal	Poland	Lamitrin Lamitrin S	Portugal	Lamictal
Romania	Lamictal	Slovak Republic	Lamictal	Slovenia	Lamictal
Spain	Lamictal	Sweden	Lamictal	United Kingdom	Lamictal

- * changes in liver function, which will show up in blood tests, or liver failure: (*see also the information at the beginning of Section 4*)
- * a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (*disseminated intravascular coagulation*): (*see also the information at the beginning of Section 4*)
- * haemophagocytic lymphohistiocytosis (HLH) (see Section 2: What you need to know before you take Lamictal)
- * changes which may show up in blood tests — including reduced numbers of red blood cells (*anaemia*), reduced numbers of white blood cells (*leucopenia*, *neutropenia*, *agranulocytosis*), reduced numbers of platelets (*thrombocytopenia*), reduced numbers of all these types of cell (*pancytopenia*), and a disorder of the bone marrow called *aplastic anaemia*
- * hallucinations ('seeing' or 'hearing' things that aren't really there)
- * confusion
- * feeling 'wobbly' or unsteady when you move about
- * uncontrollable body movements (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*choreoathetosis*), or other unusual body movements such as jerking, shaking or stiffness
- * in people who already have epilepsy, seizures happening more often
- * in people who already have Parkinson's disease, worsening of the symptoms
- * lupus-like reaction (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill-health).

Other side effects
Other side effects have occurred in a small number of people but their exact frequency is unknown:

- * There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis, or take steroids.
- * Inflammation of the kidney (*tubulointerstitial nephritis*), or inflammation of both the kidney and the eye (*tubulointerstitial nephritis and uveitis syndrome*).
- * Nightmares.
- * Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Lamictal

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Lamictal does not require any special storage conditions.

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

6 Contents of the pack and other information

What Lamictal chewable/dispersible tablets contain
The active substance is lamotrigine. Each chewable/dispersible tablet contains 100 mg lamotrigine.
The other ingredients are: calcium carbonate, low-substituted hydroxypropyl cellulose, aluminium magnesium silicate, sodium starch glycolate, povidone K30, sodium saccharine, magnesium stearate (Ph. Eur.), blackcurrant flavour.

If your seizures happen more often, or if you experience a severe seizure while you're taking Lamictal:
➡ **See a doctor as soon as possible.**

Lamictal should not be given to people aged under 18 years to treat bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behaviour in children and adolescents aged under 18 years.

Other medicines and Lamictal
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.

Your doctor needs to know if you are taking other medicines to treat epilepsy or mental health problems.
This is to make sure you take the correct dose of Lamictal. These medicines include:
* **oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide**, used to treat **epilepsy**
* **lithium, olanzapine or aripiprazole** used to treat **mental health problems**
* **bupropion**, used to treat **mental health problems** or to **stop smoking**
* **paracetamol**, used to treat **pain and fever**
➡ **Tell your doctor** if you are taking any of these.

Some medicines interact with Lamictal or make it more likely that people will have side effects. 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)
* **hormonal contraceptives**, such as **the Pill** (*see below*)
➡ **Tell your doctor** if you are taking any of these, or if you start or stop taking any.

Hormonal contraceptives (such as the Pill) can affect the way Lamictal works
Your doctor may recommend that you use a particular type of hormonal contraceptive, or another method of contraception, such as condoms, a cap or coil. If you are using a hormonal contraceptive like the Pill, your doctor may take samples of your blood to check the level of Lamictal. If you are using a hormonal contraceptive, or if you plan to start using one:
➡ **Talk to your doctor**, who will discuss suitable methods of contraception with you.

Lamictal can also affect the way hormonal contraceptives work, although it's unlikely to make them less effective. If you are using a hormonal contraceptive, and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods:
➡ **Tell your doctor**. These may be signs that Lamictal is affecting the way your contraceptive is working.

Pregnancy and breast-feeding
➡ **If you are pregnant, think you may be pregnant, or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.**
* **You should not stop treatment without discussing this with your doctor.** This is particularly important if you have epilepsy.
* Pregnancy may alter the effectiveness of Lamictal, so you may need blood tests and your dose of Lamictal may be adjusted.
* There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if Lamictal is taken during the first 3 months of pregnancy.
* Your doctor may advise you to take extra **folic acid** if you're planning to become pregnant and while you're pregnant.

➡ **If you are breast-feeding or planning to breast-feed ask your doctor or pharmacist for advice before taking this medicine.**
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, and will check your baby from time to time, whether drowsiness, rash or poor weight gain occurs, if you decide to breast-feed. Inform your doctor if you observe any of these symptoms in your baby.

Driving and using machines
Lamictal can cause dizziness and double vision.
➡ **Don't drive or use machines unless you are sure you're not affected.**
If you have epilepsy, talk to your doctor about driving and using machines.

Lamictal chewable/dispersible tablets contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Lamictal

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

How much Lamictal to take
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.**

The usual effective dose of Lamictal for adults and children aged 13 years or over is between 100 mg and 400 mg each day.

For children aged 2 to 12 years, the effective dose depends on their body weight - usually, it's between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum maintenance dose of 200 mg daily.

Lamictal is not recommended for children aged under 2 years.

How to take your dose of Lamictal
Take your dose of Lamictal once or twice a day, as your doctor advises. It can be taken with or without food.
* **Always take the full dose** that your doctor has prescribed. Never take only part of a tablet.

Your doctor may also advise you to start or stop taking other medicines, depending on what condition you're being treated for and the way you respond to treatment.

Lamictal chewable/dispersible tablets can either be swallowed whole with a little water, chewed, or mixed with water to make a liquid medicine. Never take only part of the liquid.

To chew the tablet:
You may need to drink a little water at the same time to help the tablet dissolve in the mouth. Then drink some more water to make sure all the medicine has been swallowed.

To make a liquid medicine:
* Put the tablet in a glass with at least enough water to cover the whole tablet.
* Either stir to dissolve, or wait until the tablet is fully dissolved.
* Drink all the liquid.

* Add a little more water to the glass and drink that, to make sure no medicine is left in the glass.

If you take more Lamictal than you should
➡ **Contact a doctor or nearest hospital emergency department immediately.** If possible, show them the Lamictal packet.

If you take too much **Lamictal you may be more likely to have serious side effects which may be fatal.** Someone who has taken too much Lamictal may have any of these symptoms:
* rapid, uncontrollable eye movements (*nystagmus*)
* clumsiness and lack of co-ordination, affecting their balance (*ataxia*)
* heart rhythm changes (detected usually on ECG)
* loss of consciousness, fits (convulsions) or coma.

If you forget to take a single dose of Lamictal
➡ **Don't take extra tablets to make up for a missed dose. Just take your next dose at the usual time.**
In case you forget to take multiple doses of Lamictal
➡ **Ask your doctor for advice on how to start taking it again.** It's important that you do this.

Don't stop taking Lamictal without advice
Lamictal must be taken for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you're taking Lamictal for epilepsy
To stop taking Lamictal, **it is important that the dose is reduced gradually**, over about 2 weeks. If you suddenly stop taking Lamictal, your epilepsy may come back or get worse.

If you're taking Lamictal for bipolar disorder
Lamictal may take some time to work, so you are unlikely to feel better straight away. If you stop taking Lamictal, your dose will not need to be reduced gradually. But you should still talk to your doctor first, if you want to stop taking Lamictal.

4 Possible side effects

Like all medicines, this medicine can cause side effects, but not everyone gets them.

Potentially life-threatening reactions: get a doctor's help straight away
A small number of people taking Lamictal get an allergic reaction or potentially life-threatening skin reaction, which may develop into more serious problems if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with Lamictal, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamictal is taken with another medicine called *valproate*. Some of the symptoms are more common in children, so parents should be especially careful to watch out for them.

Symptoms of these reactions include:
* **skin rashes or redness**, which may develop into life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (*Stevens–Johnson syndrome*), extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*) or extended rashes with liver, blood and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS hypersensitivity syndrome)
* **ulcers in the mouth, throat, nose or genitals**
* **a sore mouth or red or swollen eyes** (*conjunctivitis*)
* **a high temperature** (fever), flu-like symptoms or drowsiness
* **swelling around your face**, or **swollen glands** in your neck, armpit or groin

* **unexpected bleeding or bruising**, or the fingers turning blue
* **a sore throat**, or more infections (such as colds) than usual
* increased levels of liver enzymes seen in blood tests
* an increase in a type of white blood cell (eosinophils)
* enlarged lymph nodes
* involvement of the organs of the body including liver and kidneys.

In many cases, these symptoms will be signs of less serious side effects. **But you must be aware that they are potentially life-threatening and can develop into more serious problems**, such as organ failure, if they are not treated. If you notice any of these symptoms:
➡ **Contact a doctor immediately.** Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamictal. In case you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis your doctor will tell you that you must never use lamotrigine again.

Haemophagocytic lymphohistiocytosis (HLH) (see section 2: What you need to know before you take Lamictal).

Very common side effects
These may affect **more than 1 in 10** people:
* headache
* skin rash.

Common side effects
These may affect **up to 1 in 10** people:
* aggression or irritability
* feeling sleepy or drowsy
* feeling dizzy
* shaking or tremors
* difficulty in sleeping (*insomnia*)
* feeling agitated
* diarrhoea
* dry mouth
* feeling sick (*nausea*) or being sick (*vomiting*)
* feeling tired
* pain in your back or joints, or elsewhere.

Uncommon side effects
These may affect up to **1 in 100** people:
* clumsiness and lack of co-ordination (*ataxia*)
* double vision or blurred vision
* unusual hair loss or thinning (*alopecia*)
* skin rash or sunburn after exposure to sun or artificial light (*photosensitivity*)

Rare side effects
These may affect **up to 1 in 1,000** people:
* a life-threatening skin reaction (*Stevens–Johnson syndrome*): (*see also the information at the beginning of Section 4*).
* 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*). These symptoms usually disappear once treatment is stopped however if the symptoms continue or get worse **contact your doctor**.
* rapid, uncontrollable eye movements (*nystagmus*)
* itchy eyes, with discharge and crusty eyelids (*conjunctivitis*).

Very rare side effects
These may affect **up to 1 in 10,000** people:
* a life-threatening skin reaction (*toxic epidermal necrolysis*): (*see also the information at the beginning of Section 4*)
* Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): (*see also the information at the beginning of Section 4*)
* a high temperature (*fever*): (*see also the information at the beginning of Section 4*)
* swelling around the face (*oedema*) or swollen glands in the neck, armpit or groin (*lymphadenopathy*): (*see also the information at the beginning of Section 4*)