

Lamictal® 25 mg Tablets

lamotrigine

Package leaflet: Information for the User

Your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun (e.g. use of a sunscreen and/or to wear protective clothing)

- * **if you have ever developed meningitis after taking lamotrigine (read the description of these symptoms in Section 4 of this leaflet. Rare side effects)**
- * **if you are already taking medicine that contains lamotrigine. Problems.** Brugada syndrome is a genetic disease that results in abnormal electrical activity within the heart. ECG abnormalities which may lead to arrhythmias (abnormal heart rhythm) can be triggered by lamotrigine.

If any of these applies to you:

- ➡ **Tell your doctor,** who may decide to lower the dose, or that Lamictal is not suitable for you.

Important information about potentially life-threatening reactions

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 can include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to know the symptoms to look out for while you are taking Lamictal.

- ➡ **Read the description of these symptoms in Section 4 of this leaflet** under ‘*Potentially life-threatening reactions: get a doctor’s help straight away*’.

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, disturbances of brain function).

Thoughts of harming yourself or suicide

Anti-epileptic medicines are used to treat several conditions, including bipolar disorder, you may be more likely to think like this:

- * if you have previously had thoughts about harming yourself or about suicide
- * if you are under 25 years old.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you’re taking Lamictal:

- ➡ **See a doctor as soon as possible or go to the nearest hospital for help.**

You may find it helpful to tell a family member, caregiver or close friend that you can become depressed or have significant changes in mood, and ask them to read this leaflet. You might ask them to tell you if they are worried about your depression or other changes in your behaviour.

A small number of people being treated with anti-epileptics such as Lamictal have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

If you’re taking Lamictal for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you’re taking Lamictal. Some patients may experience severe seizures, which may cause serious health problems. If you’re taking Lamictal:

- ➡ **See a doctor as soon as possible.**

The manufacturer is: Manufacturer: GlaxoSmithKline Pharmaceuticals S.A., Ul. Grunwaldzka 189, 60-322 Poznan, Poland.

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

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

Blind or partially sighted?

Is this leaflet hard to see or read?

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

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

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*).
- * 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 HPRaPharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

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.

Contents of the pack and other information

What Lamictal tablets contain

The active substance is lamotrigine. Each tablet contains 25 mg, lamotrigine. The other ingredients are: lactose monohydrate, microcystalline cellulose, povidone K30, sodium starch glycolate (Type A), iron oxide yellow (E172) and magnesium stearate.

What Lamictal tablets look like and contents of the pack

Lamictal tablets (all strengths) are square with rounded corners, and pale, yellowish brown in colour.

Lamictal 25mg tablets are marked ‘GSEC7’ on one side and ‘25’ on the other. Each pack contains blisters of 56 tablets.

Parallel Product Authorisation Holder: Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

Repackaged by: Lexon Pharmaceuticals (Ireland) Limited, Units 22 & 25, Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland. Dublin 17, Ireland.

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

What Lamictal is and what it is used for

What you need to know before you take Lamictal

How to take Lamictal

Possible side effects

How to store Lamictal

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;
- * **if you experience a rash or sunburn after taking lamotrigine and having been exposed to sun or artificial light** (e.g. solarium).

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 arpiprazole** used to treat mental health problems
 - * **dipropion**, 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, 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 sample 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.

Important information about some of the ingredients of Lamictal
Lamictal tablets contain small amounts of a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Lamictal 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
It can be taken with or without food.
➔ **Tell your doctor** if possible, show them the Lamictal packet.
➔ **Contact a doctor or nearest hospital emergency department immediately.** If you take too much Lamictal you may be more likely to have serious side effects which may be fatal.
➔ **Contact a doctor or nearest hospital emergency department immediately.** If possible, show them the Lamictal packet.
➔ **Swallow your tablets whole.** Don't break, chew or crush them.
➔ **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.
➔ **Swallow your tablets whole.** Don't break, chew or crush them.
➔ **Always take the full dose** that your doctor has prescribed. Never take only part of a tablet.
If you take too much Lamictal you may be more likely to have serious side effects which may be fatal.

* 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. 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
- * **ulcers in the mouth, throat, nose or genitals** (conjunctivitis)
- * **a high temperature** (fever), flu-like symptoms or drowsiness
- * **unexplained 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.

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)
* 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)
* 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
* hallucinations ('seeing' or 'hearing' things that aren't really there)
* feeling 'wobbly' or unsteady when you move about
* uncontrollable body movements (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*chorea/athetosis*), or other unusual body movements such as jerking, shaking or stiffness

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