

FLAT DIMENSION = 180 x 590mm
FOLDED DIMENSION = 180 x 37mm

30 mm

10 mm

PACKAGE LEAFLET: INFORMATION FOR USER

LAMOTRIGINE BRISTOL LABS 25MG TABLETS
LAMOTRIGINE BRISTOL LABS 50MG TABLETS
LAMOTRIGINE BRISTOL LABS 100MG TABLETS
LAMOTRIGINE BRISTOL LABS 200MG 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, pharmacist or nurse.
- 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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Lamotrigine tablets is and what it is used for
- What you need to know before you take Lamotrigine tablets
- How to take Lamotrigine tablets
- Possible side effects
- How to store Lamotrigine tablets
- Contents of the pack and other information

1. What Lamotrigine tablets is and what it is used for

The name of your medicine is Lamotrigine 25mg or 50mg or 100mg or 200mg Tablets. The active ingredient is Lamotrigine.

Lamotrigine belongs to a group of medicines called *anti-epileptics*. It is used to treat two conditions – **epilepsy** and **bipolar disorder**.

Lamotrigine **treats epilepsy** by blocking the signals in the brain that trigger epileptic seizures (fits).

- For adults and children aged 13 years and over, lamotrigine can be used on its own or with other medicines, to treat epilepsy. Lamotrigine 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, lamotrigine 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.

Lamotrigine 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, lamotrigine 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 lamotrigine works in the brain to have this effect.

2. What you need to know before you take Lamotrigine tablets

Do not take Lamotrigine tablets 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 Lamotrigine

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking Lamotrigine tablets.

- 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)**. 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 medicines that contains lamotrigine**
- if you have a condition called **Brugada syndrome, or other heart problem**. 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 Lamotrigine is not suitable for you.

Important information about potentially life-threatening reactions

A small number of people taking Lamotrigine 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 Lamotrigine. These include skin rashes or redness, ulcers in the mouth or throat, sore mouth or throat, red or swollen eyes, fever, swelling around your face, swollen glands, unexpected bleeding or bruising.

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

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 lamotrigine.

If you notice any of these symptoms:

- See a doctor as soon as possible**. Your doctor may decide to carry out tests on your liver, kidney or blood, and may tell you to stop taking lamotrigine.

Thoughts of harming yourself or suicide

Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. People with bipolar disorder can sometimes have thoughts of harming themselves or committing suicide. If you have bipolar disorder, you may be more likely to think like this:

- when you first start treatment
- 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 Lamotrigine, 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 with epilepsy being treated with Lamotrigine have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Lamotrigine 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.

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).

If you’re taking Lamotrigine for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you’re taking Lamotrigine. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a severe seizure while you’re taking Lamotrigine. See a doctor as soon as possible.

Other medicines and Lamotrigine Tablets

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.

It is important to tell your doctor or pharmacist if you are taking any other medicines for epilepsy at the same time as lamotrigine if you are pregnant, think you may be pregnant, or are planning to have a baby (see also the information in Section 2 on pregnancy and breast-feeding).

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 lamotrigine. 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 Lamotrigine or make it more likely that you’ll have side effects. These include:

- valproate or carbamazepine for epilepsy and mental health problems
- phenytoin, primidone or phenobarbitone for epilepsy
- risperidone for mental health problems
- rifampicin, an antibiotic
- a combination of lopinavir and ritonavir or, atazanavir and ritonavir used to treat Human Immunodeficiency Virus (HIV) infection
- oestrogen-containing products, including hormonal contraceptives, such as the Pill (see below) and hormone replacement therapy (HRT).

Tell your doctor if you are taking, or if you start or stop taking, any of these.

Hormonal contraceptives (such as the Pill) can affect the way Lamotrigine 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 a coil. If you are using a hormonal contraceptive like the Pill, your doctor may take samples of your blood to check the level of lamotrigine. 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. Lamotrigine can also affect the way hormonal contraceptives work, although it’s unlikely to make them less effective. If you are using 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 lamotrigine is affecting the way your contraceptive is working.

HRT can affect the way Lamotrigine works

If you are using oestrogen-containing hormone replacement therapy (HRT), your doctor may take samples of your blood to check the level of Lamotrigine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking medicine. If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

- 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 Lamotrigine, so you may need blood tests and your dose of Lamotrigine may be adjusted.
- Studies of women who took lamotrigine at usual doses while they were pregnant have not shown an increased risk of physical birth abnormalities.
- The risk of physical birth abnormalities may increase when higher doses of epilepsy medicines are taken or more than one epilepsy medicine is used at the same time. Where possible, your doctor will consider using one epilepsy medicine at the lowest effective dose to control your epilepsy.
- There may be a small increased risk of birth defects, including a cleft lip or cleft palate, if Lamotrigine 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 Lamotrigine passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast-feeding while you’re taking Lamotrigine 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

- Lamotrigine can cause dizziness and double vision.
- Don’t drive or operate machines unless you are sure you’re not affected.
- If you have epilepsy, talk to your doctor about driving and using machines.

Lamotrigine tablets contain 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.

Information on sodium content:

Lamotrigine tablets contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Lamotrigine tablets

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 lamotrigine to take

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

- your age
- whether you are taking lamotrigine with other medicines
- whether you have problems with your kidneys or liver

Your doctor will start you on a low dose, and gradually increase the dose over a few weeks until you reach a dose that works for you (called the *effective dose*).

Same Size Artwork
Size: 590 x 180 mm
Front

590 mm

180 mm

