

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**LAMAL® , 25 mg; 50 mg; 100 mg and 200 mg tablets**  
**(lamotrigine)**

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Lamal is and what it is used for
2. Before you take Lamal
3. How to take use Lamal
4. Possible side effects
5. How to store Lamal
6. Further information

**1. WHAT LAMAL IS AND WHAT IT IS USED FOR?**

Lamal (lamotrigine) belongs to a group of medicines called antiepileptic drugs used to treat epilepsy and bipolar disorders.

**Epilepsy:**

Lamal treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits). Lamal may be used as monotherapy (on its own) or with other medicines to treat adults and children over 12 years of age. Lamal can also be used in combination with other anti-epileptic medicines in both adults and children aged 2 years and over. Lamal can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut syndrome.

**Bipolar Disorder:**

Lamal is used in adult patients (over 18 years) to treat bipolar disorders. Lamal 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 Lamal works in the brain to have this effect. Lamal should not be used in patients under 18 years for treating bipolar disorders.

Some medicines used to treat depression have been associated with suicidal thoughts and suicidal behavior in children or teenagers.

## 2. BEFORE YOU TAKE LAMAL

### Do not take Lamal

- if you are allergic (hypersensitive) to lamotrigine or any of the other ingredients of Lamal.

If this applies to you:

Tell your doctor, and don't take Lamal.

### Take special care with Lamal

#### Your doctor needs to know before you take Lamal:

- **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 after taking lamotrigine** (*read the description of these symptoms in Section 4 of this leaflet: possible side effects*)
- **if you are already taking medicine that contains lamotrigine.**

If any of these applies to you:

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

#### Important information about potentially serious reactions

A small number of people taking Lamal get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the symptoms to look out for while you are taking Lamal.

**Read the description of these symptoms in Section 4 of this leaflet** under '*Potentially serious reactions: get a doctor's help straight away*'.

#### 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 have these thoughts:

- when you first start treatment
- if you have previously had thoughts about harming yourself or about suicide
- if you are under 25 years of age.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking Lamal **see a doctor as soon as possible or go to the nearest hospital for help.**

A small number of people being treated with anti-epileptics such as Lamal 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 Lamal for epilepsy**

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking Lamal. 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 Lamal **see a doctor as soon as possible**.

### **Lamal 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.

### **Taking other medicines**

*Tell your doctor or pharmacist if you're taking any other medicines, have taken any recently, or start taking new ones - these include herbal medicines or other medicines you 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 Lamal. These medicines include:

**oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide**, used to treat **epilepsy**

**lithium or olanzapine**, used to treat **mental health problems**

**bupropion**, used to treat **mental health problems** or to **stop smoking**

**Tell your doctor** if you are taking any of these.

Some medicines interact with Lamal 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 Lamal 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 Lamal. 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.

Lamal 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 Lamal is affecting the way your contraceptive is working.

### **Taking Lamal with food and drink**

Lamal tablets may be taken with or without food. During the therapy with Lamal you should not use alcohol drinks.

### **Pregnancy and breastfeeding**

**Talk to your doctor if you are pregnant, might be pregnant or are planning on becoming pregnant.** It's important that you do this because there may be an increased risk of birth defects in babies whose mothers took Lamal during pregnancy. These defects include cleft lip or cleft palate. Your doctor may advise you to take extra **follic acid** if you're planning to become pregnant and while you're pregnant.

**Talk to your doctor if you're breast feeding or planning to breast feed.**

The active ingredient of Lamal passes into breast milk and may affect your baby. Your Doctor will discuss the risks and benefits of breast feeding while you're taking Lamal and will check your baby from time to time if you decide to breastfeed.

### **Driving and using machines**

Lamal 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.**

## **3. HOW TO TAKE LAMAL**

*Always take Lamal exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.*

Your doctor may give you different instructions to those written below.

The dose your doctor will prescribe for you depends on whether you are taking any other medicines and if so which ones. This is especially important if you are taking any medicine containing valproate.

Lamal is administered either as monotherapy or as adjuvant therapy with other antiepileptics. The therapy is started with lower doses and gradually increased to an optimal therapeutic effect.

### **Epilepsy**

#### ***Adults and children over 12 years old:***

The usual dose to control epilepsy is between 100 mg and 400 mg, taken once daily or in two divided doses. When you first start taking Lamal, your doctor will prescribe a much lower dose than this and then increase your dose gradually over a few weeks.

#### ***Children between 2 and 12 years of age:***

The usual dose to control epilepsy is between 1 mg and 15 mg per kilogram of your child's body weight, taken once daily or in two divided doses. The dose may be increased up to 400mg daily dose depending on your child's therapeutic response. When your child first starts taking Lamal, your doctor will prescribe a much lower dose than this for your child and will then increase it gradually over a few weeks.

#### ***Lamal is not recommended in children under 2 years of age.***

If you or your child has liver disease your doctor may prescribe less than the recommended dose, depending on how severe the liver condition is.

### **How to take your dose of Lamal**

Take your dose of Lamal once or twice a day, as your doctor advises. It can be taken with or without food.

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 Lamal does not control your seizures or if you have more seizures than before started the medicine, talk to your doctor.

### **Bipolar disorders**

#### ***Adults (over 18 years old)***

The usual dose for bipolar disorders is between 100 mg and 400 mg, taken once daily or in two divided doses. When you first start taking Lamal, your doctor will prescribe a much lower dose than this and then increase your dose gradually in a period of 6 weeks.

#### ***Children (under 18 years old)***

Lamal is not recommended for treating bipolar disorders in patients less than 18 years of age.

### **If you take more Lamal than you should**

If you take too much of Lamal tablets you should seek your doctor or pharmacist immediately. Symptoms of overdose may include: unusual dizziness, severe headache, unusual sleepiness, and loss of consciousness.

### **If you forget to take Lamal**

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

### **If you stop taking Lamal**

Abrupt discontinuation of Lamal therapy increases the incidence of seizures.

Unless safety concerns require a more rapid withdrawal, the dose of lamotrigine should be tapered over a period of at least 2 weeks.

*If you have any further questions on the use of this product, ask your doctor or pharmacist.*

## **4. POSSIBLE SIDE EFFECTS**

*Like all medicines, Lamal can cause side effects, although not everybody gets them.*

### **Potentially serious reactions: get a doctor's help straight away**

A small number of people taking Lamal get an allergic reaction or potentially serious 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 Lamal, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamal 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 severe 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*)

**a sore mouth or eyes**

**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.

In many cases, these symptoms will be signs of less serious side effects. **But you must be aware that they are potentially serious 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 Lamal.

#### - **Very common side effects**

These may affect **more than 1 in 10** people:

headache

feeling dizzy

feeling sleepy or drowsy

clumsiness and lack of co-ordination (*ataxia*)

double vision or blurred vision

feeling sick (*nausea*) or being sick (*vomiting*)

skin rash.

#### **Common side effects**

These may affect **up to 1 in 100** people:

aggression or irritability

rapid, uncontrollable eye movements (*nystagmus*)

shaking or tremors

difficulty in sleeping

diarrhoea

dry mouth

feeling tired

pain in your back or joints, or elsewhere.

#### **Rare side effects**

These may affect **up to 1 in 1,000** people:

itchy eyes, with discharge and crusty eyelids (*conjunctivitis*)

a severe skin reaction (*Stevens-Johnson syndrome*: see also the information at the beginning of Section 4).

#### **Very rare side effects**

These may affect **up to 1 in 10,000** people:

hallucinations ('seeing' or 'hearing' things that aren't really there)

confusion or agitation

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

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*)

a severe skin reaction (*toxic epidermal necrolysis: see also the information at the beginning of Section 4*)

in people who already have epilepsy, seizures happening more often

changes in liver function, which will show up in blood tests, or liver failure

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*

a serious disorder of blood clotting, which can cause unexpected bleeding or bruising (*disseminated intravascular coagulation*)

a high temperature (*fever*)

swelling around the face (*oedema*) or swollen glands in the neck, armpit or groin (*lymphadenopathy*)

in people who already have Parkinson's disease, worsening of the symptoms.

*If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

## 5. HOW TO STORE LAMAL

### **Keep out of the reach and sight of children.**

This medicinal product does not require any special storage conditions.

Do not use Lamal after the expiry date which is stated on the carton (abbreviation used for expiry date). The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### **What Lamal contains**

- The active substance is lamotrigine.

Each tablet contains 25 mg, 50 mg, 100 mg and 200 mg of lamotrigine.

- The other ingredients are: calcium carbonate; aluminium magnesium silicate; sodium starch glycolate; low-substituted hydroxypropyl cellulose; povidone; cellulose, microcrystalline; saccharin sodium; flavour blackcurrant; silica, colloidal anhydrous; magnesium stearate.

### **What Lamal looks like and contents of the pack**

Lamal 25 mg are white, round, biconvex tablets.

Lamal 50 mg, 100 mg, 200 mg are white, round, biconvex tablets with bisection line on one side.

Lamal 25 mg, 50 mg in PVC/Al foil blisters containing 30 tablets (3 blisters x 10 tablets), in a box with a leaflet inside.

Lamal 100 mg, 200 mg in PVC/Al foil blisters containing 30 tablets (2 blisters x 15 tablets), in a box with a leaflet inside.

### **Marketing Authorisation Holder and Manufacturer**

#### *Manufacturer*

ALKALOID- INT d.o.o.  
Šlandrova ulica 4  
1231 Ljubljana – Črnuče, Slovenia

For any information about this medicinal product, please contact the Marketing Authorisation Holder:

#### *Marketing authorization holder*

ALKALOID Ltd  
Motopista 2, 2 "Ricardo Vakarini" Str., fl. 3, ap.10  
Sofia 1404, Republic of Bulgaria  
tel. +359 2 80 81 081  
+359 2 80 81 099  
fax: +359 2 95 89 367  
e-mail: office@alkaloid.bg

**This leaflet was last approved in**