

## Package leaflet: Information for the user

**Lamotrigine Aurobindo 25 mg tablets**

**Lamotrigine Aurobindo 50 mg tablets**

**Lamotrigine Aurobindo 100 mg tablets**

**Lamotrigine Aurobindo 200 mg 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 same as yours.
- If you get any 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 Lamotrigine Aurobindo is and what it is used for
- 2 What you need to know before you take Lamotrigine Aurobindo
- 3 How to take Lamotrigine Aurobindo
- 4 Possible side effects
- 5 How to store Lamotrigine Aurobindo
- 6 Contents of the pack and other information

### **1. What Lamotrigine Aurobindo is and what it is used for**

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

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

- For adults and children aged 13 years and over, Lamotrigine Aurobindo can be used on its own or with other medicines, to treat epilepsy. Lamotrigine Aurobindo 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 Aurobindo 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 Aurobindo 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 Aurobindo 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 Aurobindo works in the brain to have this effect.

### **2. What you need to know before you take Lamotrigine Aurobindo**

#### **Do not take Lamotrigine Aurobindo:**

Lamotrigine 25/50/200 mg tablets

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

## Lamotrigine 100 mg tablets

- if you are **allergic** to lamotrigine, sunset yellow aluminium lake 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 Aurobindo.

### Warnings and precautions

#### Talk to your doctor or pharmacist before taking Lamotrigine

- 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: Rare 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 Lamotrigine Aurobindo is not suitable for you.

#### Important information about potentially serious 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.

→ **Read the description of these symptoms in section 4 of this leaflet** under '*Potentially life-threatening 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 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 being treated with anti-epileptics such as Lamotrigine Aurobindo 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 Lamotrigine Aurobindo for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while

you're taking Lamotrigine Aurobindo. 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 Aurobindo:

➔ **See a doctor as soon as possible.**

### **Lamotrigine Aurobindo 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 Lamotrigine Aurobindo**

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

Your doctor need 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

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

Some medicines interact with Lamotrigine Aurobindo 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 Lamotrigine Aurobindo 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 Aurobindo. 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 Aurobindo 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 Lamotrigine Aurobindo is affecting the way your contraceptive is working.

### **Pregnancy and breast feeding**

**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 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 Lamotrigine, so you may need blood tests and your dose of Lamotrigine may be adjusted.
- 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 Aurobindo 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 Aurobindo, and will check your baby from time to time if you decide to breast feed.

### **Driving and using machines**

Lamotrigine Aurobindo 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 Aurobindo tablets contains lactose**

Lamotrigine Aurobindo tablets contain small amounts of a sugar called lactose. If you have an intolerance to lactose or any other sugars: **Tell your doctor**, and don't take Lamotrigine Aurobindo.

Lamotrigine Aurobindo 100 mg tablets contain sunset yellow aluminium lake, which may cause allergic reactions.

## **3. How to take Lamotrigine Aurobindo**

Always Take this medicine exactly as your doctor has told you . Check with your doctor or pharmacist if you're not sure.

### **How much Lamotrigine Aurobindo to take**

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

- your age
- whether you are taking Lamotrigine Aurobindo 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 Lamotrigine Aurobindo than your doctor tells you to.**

The recommended effective dose of Lamotrigine Aurobindo for adults and children aged over 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.

Lamotrigine is not recommended for children aged under 2 years.

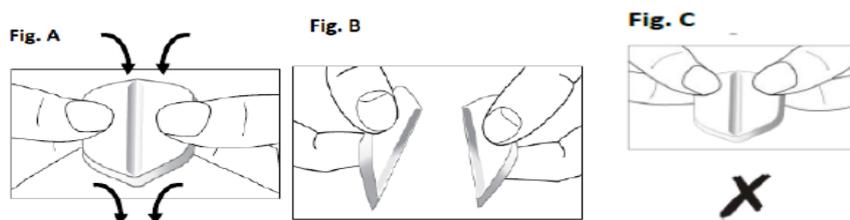
### **How to take your dose of Lamotrigine Aurobindo**

Take your dose of Lamotrigine Aurobindo 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. If you need to halve your tablets (to take half the dose for the 25 and 100mg strengths or for ease of swallowing for the 25, 100 and 200mg strengths), then swallow tablet halves whole. Remember not to chew or crush them. See diagrams below.
- Always **take the full dose** that your doctor has prescribed. Never take only part of a tablet.

#### How to halve the tablets (25 mg, 100 mg & 200 mg only).



Use a tablet cutter to halve tablets. Alternatively, keeping the score-line side facing upwards, hold both the upper and lower sides of the tablet, on either side of the score-line, using the thumb and index finger of both hands [fig. A] and halve the tablet by pressing down and away from the score-line so that the tablet opens at the score-line side [fig. B]. Do not hold on to the shoulder (end) of the tablet, on either side of the score-line [fig. C], when halving since this may cause the tablet to crumble.

#### If you take more Lamotrigine Aurobindo than you should

➔ **Contact a doctor or nearest hospital emergency department immediately.** If possible, show them the Lamotrigine Aurobindo packet.

If you take too much **Lamotrigine** you may be more likely to have serious side effects which may be fatal.

Someone who has taken too much Lamotrigine Aurobindo 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 Lamotrigine Aurobindo

**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 Lamotrigine

➔ **Ask your doctor for advice on how to start taking it again.** It's important that you do this.

#### Don't stop taking Lamotrigine Aurobindo without advice

Lamotrigine Aurobindo must be taken for as long as your doctor recommends. Don't stop unless your doctor advises you to.

#### If you are taking Lamotrigine Aurobindo for epilepsy

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

#### If you are taking Lamotrigine Aurobindo for bipolar disorder

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

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### **Potentially life-threatening reactions: get a doctor's help straight away**

A small number of people taking Lamotrigine Aurobindo 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 Lamotrigine, especially if the starting dose is too high or if the dose increased too quickly, or if Lamotrigine 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 Lamotrigine Aurobindo. 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** (may affect **more than 1 in 10** people):

- headache
- skin rash.

**Common** (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** ( 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).

**Rare** ( 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** (may affects **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)
- 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)
- 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 antiepileptic medication, have a history of osteoporosis, or take steroids.
- Nightmares.

### **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

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Lamotrigine Aurobindo**

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 blister/label of the bottle and the carton after the EXP. The expiry date refers to the last day of that month.

This medicinal product 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. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Lamotrigine Aurobindo tablets contain**

- The active substance is lamotrigine.  
Each tablet contains 25 mg lamotrigine.  
Each tablet contains 50 mg lamotrigine.  
Each tablet contains 100 mg lamotrigine.  
Each tablet contains 200 mg lamotrigine.
- The other ingredients are Cellulose microcrystalline, lactose monohydrate, indigo carmine aluminium lake (E132) (For 200 mg only), sunset yellow aluminium lake (E110) (For 100 mg only), sodium starch glycolate (Type A), magnesium stearate, povidone (K30).

### **What Lamotrigine Aurobindo tablets look like and contents of the pack**

Tablet.

Lamotrigine Aurobindo 25 mg tablets are white to off white coloured, shield shaped uncoated tablets debossed with 'D' and '93' on one side and scoreline on the other side.

The tablet can be divided into equal doses.

Lamotrigine Aurobindo 50 mg tablets are white to off white coloured, rounded square uncoated tablets debossed with 'D' on multifaceted side and '97' on the flat side.

Lamotrigine Aurobindo 100 mg tablets are peach coloured, mottled, shield shaped uncoated tablets debossed with 'D' and '94' on one side and scoreline on the other side.

The tablet can be divided into equal doses

Lamotrigine Aurobindo 200 mg tablets are blue coloured, mottled, shield shaped uncoated tablets debossed with 'D' and '96' on one side and scoreline on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Lamotrigine Aurobindo tablets are available in:

- Clear PVC/Aluminium foil blisters  
Pack sizes: 1, 7, 10, 14, 20, 21, 28, 30, 40, 42, 46, 50, 56, 60, 90, 98, 100, 200, 250, 500 tablets.
- HDPE bottles with polypropylene cap and cotton coil  
Pack sizes: 60, 90, 100, 250, 500, 1000 tablets.

Not all pack sizes may be marketed.

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

#### **Marketing Authorisation Holder:**

Aurobindo Pharma Limited  
Ares, Odyssey Business Park  
West End Road, South Ruislip HA4 6QD  
United Kingdom

#### **Manufacturer:**

Milpharm Limited  
Ares, Odyssey Business Park  
West End Road  
South Ruislip HA4 6QD  
United Kingdom

or

APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far  
Birzebbugia, BBG 3000  
Malta

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

Czech Republic	Lamotrigine Aurobindo 25 mg/ 50 mg/ 100 mg tablety
Denmark	Lamotrigin "Aurobindo"
Germany	Lamotrigin Aurobindo 25 mg/ 50 mg/ 100 mg/ 200 mg Tabletten
Greece	ISLETON 25 mg/ 50 mg/ 100 mg/ 200 mg δισκία
Ireland	Lamotrigine Aurobindo 25 mg/ 50 mg/ 100 mg/ 200 mg tablets
Poland	Verpin
Portugal	Lamotrigina Aurobindo
Sweden	Lamotrigin Aurobindo 25 mg/ 50 mg/ 100 mg/ 200 mg tabletter
United Kingdom	Lamotrigine Milpharm 25 mg/ 50 mg/ 100 mg/ 200 mg tablets

**This leaflet was approved in 11/2017.**