

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..

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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

Your doctor needs to know before you take Lamotrigine Aurobindo:

- ☐ ☐ ☐ **if you have any kidney problems**
- ☐ ☐ ☐ **if you have ever developed a rash** after taking lamotrigine or other medicines for epilepsy
- ☐ ☐ ☐ **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

- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Lamotrigine Aurobindo, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.
- The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Lamotrigine Aurobindo, you must not be re-started on Lamotrigine Aurobindo at any time

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

- If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

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.**

A small number of people being treated with anti-epileptics such as Lamotrigine Aurobindo have also had thoughts of harming or killing themselves. If 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 — 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 Lamotrigine. 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 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**
- ☐ a combination of **lopinavir and ritonavir**, used to treat **Human Immunodeficiency Virus (HIV) infection**
- ☐ **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

➔ There may be an increased risk of birth defects in babies whose mothers took Lamotrigine Aurobindo during pregnancy. These defects include cleft lip or cleft palate. Your doctor may advise you to take extra **folic acid** if you're planning to become pregnant and while you're pregnant.

Pregnancy may also alter the effectiveness of Lamotrigine Aurobindo, so you may need blood tests and your dose of Lamotrigine may be adjusted

➔ **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.

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

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 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.

For doses not realisable/practicable with this strength other strengths of this medicinal product are available.

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 usual 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 of 400 mg daily. Lamotrigine is not recommended for children aged under 2 years.

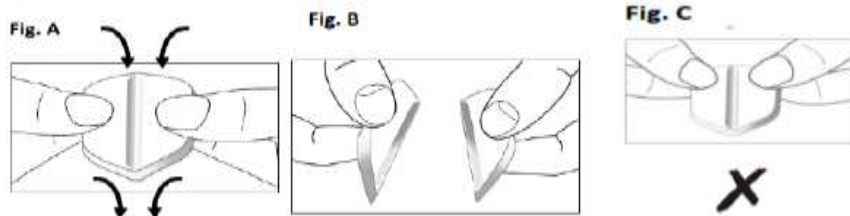
How to take your dose of Lamotrigine Aurobindo

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.

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 pharmacist immediately.** If possible, show them the Lamotrigine Aurobindo packet.

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*)
- ☐ loss of consciousness or coma.

If you forget to take Lamotrigine Aurobindo

Don't take extra tablets or a double dose to make up for a forgotten dose.

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

A small number of people taking Lamotrigine Aurobindo get an allergic reaction or potentially serious skin reaction, which may develop into more serious, and even life-threatening, 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 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 Lamotrigine Aurobindo.

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 10** 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*)
- ☐ Potentially life-threatening skin rashes (*Stevens-Johnson syndrome*) have been reported (see section 2).

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
- Potentially life-threatening skin rashes (Toxic epidermal necrolysis) have been reported (see section 2).
 - ☐ 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*, *agranulo-cytosis*), 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.

Other side effects

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

- 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*).

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.

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

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.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
Hungary	Lamotrigin Aurobindo 50 mg/ 100 mg tabletta
Ireland	Lamotrigine Aurobindo 25 mg/ 50 mg/ 100 mg/ 200 mg tablets
Poland	Lamotrigine Aurobindo
Portugal	Lamotrigina Aurobindo
Slovakia	Lamotrigin Aurobindo 25 mg/ 50 mg/ 100 mg tablety
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 06/2014.