

Package leaflet: Information for the user

Lamotrigine Aurobindo 5 mg dispersible/chewable tablets
Lamotrigine Aurobindo 25 mg dispersible/chewable tablets
Lamotrigine Aurobindo 50 mg dispersible/chewable tablets
Lamotrigine Aurobindo 100 mg dispersible/chewable tablets
Lamotrigine Aurobindo 200 mg dispersible/chewable 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 the same as yours.
- If 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

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 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

- if you are **allergic** 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 Aurobindo

Warnings and precautions

- **Talk to your doctor or pharmacist before taking Lamotrigine Aurobindo: 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: Other 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 Aurobindo 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 Aurobindo.

➔ **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 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 Aurobindo:

➔ **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 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 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 Aurobindo.

These medicines include:

- **oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide**, used to treat **epilepsy**
 - **lithium or 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 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, breast-feeding and fertility

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 Aurobindo may be adjusted.

- ➔ **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.
- ➔ **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.

3. How to take Lamotrigine Aurobindo

Always use this medicine exactly as your doctor or pharmacist has told you to. 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 usual effective dose of Lamotrigine Aurobindo 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 of 400 mg daily.

Lamotrigine Aurobindo 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.

- **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.

Lamotrigine Aurobindo dispersible/chewable tablets can either be swallowed whole with a little water, chewed, or mixed with water to make a liquid medicine.

To chew the tablet:

You may need to drink a little water at the same time to help the tablet dissolve in the mouth. Then drink some more water to make sure all the medicine has been swallowed.

To make a liquid medicine:

- Put the tablet in a glass with at least enough water to cover the whole tablet.
- Either stir to dissolve, or wait until the tablet is fully dissolved.
- Drink all the liquid.

- Add a little more water to the glass and drink that, to make sure no medicine is left in the glass.

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 Aurobindo 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 Lamotrigine Aurobindo

Do not take 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're 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're 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 problems if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with Lamotrigine Aurobindo, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamotrigine Aurobindo 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) or extended rashes with liver, blood and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as 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 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. 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
- feeling dizzy
- feeling sleepy or drowsy
- feeling sick (nausea) or being sick (vomiting)
- skin rash.

Common side effects

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

- aggression or irritability
- feeling sleepy or drowsy
- feeling dizzy
- 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.

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

- 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)
- 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 or nurse. 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

e-mail:

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

This medicine does not require any special storage conditions.

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. Contents of the pack and other information

What Lamotrigine Aurobindo contains

The active substance is lamotrigine. Each dispersible/chewable tablet contains 5 mg, 25 mg, 50 mg, 100 mg or 200 mg lamotrigine.

- The other ingredients are cellulose microcrystalline, magnesium Carbonate heavy, polacrillin, potassium, sucralose, povidone (K-30), magnesium stearate, black currant flavor (maltodextrin, artificial flavors, triacetin, benzyl alcohol, acetic acid & caramel color).

What Lamotrigine Aurobindo looks like and contents of the pack

Dispersible/chewable tablet

Lamotrigine Aurobindo 5 mg dispersible/chewable tablets

White to off-white, capsule shaped uncoated tablets debossed with 'H' on one side and '81' on other side.

Lamotrigine Aurobindo 25 mg dispersible/chewable tablets

White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '80' on flat side.

Lamotrigine Aurobindo 50 mg dispersible/chewable tablets

White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '79' on flat side.

Lamotrigine Aurobindo 100 mg dispersible/chewable tablets

White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '78' on flat side.

Lamotrigine Aurobindo 200 mg dispersible/chewable tablets

White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '77' on flat side.

Packaging:

Contents of packaging

PVC/Aclar/Al blister:

7, 10, 14, 20, 21, 28, 30, 40, 42, 50, 56, 60, 90, 98, 100, 200 tablets

HDPE Bottle:

Lamotrigine Aurobindo 25 mg, 50 mg & 100 mg : 30, 90, 100 & 200 tablets

Lamotrigine Aurobindo 200 mg: 30, 90, 100 & 200 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

APL Swift Services (Malta) Limited
HF 26, 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:

France	Lamotrigine Arrow Lab 25 mg/ 50 mg/ 100 mg/ 200 mg comprimé dispersible
Germany	Lamotrigin Aurobindo 5 mg Tabletten zur Herstellung einer Suspension zum Einnehmen
Ireland	Lamotrigine Aurobindo 5 mg/ 25 mg/ 50 mg/ 100 mg/ 200 mg dispersible/chewable tablets
Italy	Lamotrigina Aurobindo 5 mg/ 25 mg/ 50 mg/ 100 mg/ 200 mg compresse dispersibili
Malta	Lamotrigine Aurobindo 50 mg/ 100 mg/ 200 mg dispersible tablets
Netherlands	Lamotrigine Aurobindo 5 mg/ 25 mg/ 50 mg/ 100 mg/ 200 mg disperseerbare tabletten

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