

PACKAGE LEAFLET – INFORMATION FOR THE USER

Lamotrigine Accord 25mg Tablets
Lamotrigine Accord 50mg Tablets
Lamotrigine Accord 100mg Tablets
Lamotrigine Accord 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 you doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Lamotrigine Tablets are and what they are used for
2. What you need to know before you take Lamotrigine Tablets
3. How to take Lamotrigine Tablets
4. Possible side effects
5. How to store Lamotrigine Tablets
6. Contents of the pack and other information

1. What Lamotrigine Tablets are and what they are used for

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

Lamotrigine works by blocking the signals in the brain that trigger epileptic seizures (fits).

Lamotrigine used to treat epilepsy.

- For adults and children aged 13 years and over, Lamotrigine can be used alone or in combination with other anti-epileptic medicines. Lamotrigine can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut Syndrome.
- For children aged 2 to 12 years, Lamotrigine can be used with other medicines, to treat those conditions. Lamotrigine can be used alone to treat a type of epilepsy called typical absence seizures.

Lamotrigine is also used to treat 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 alone or in combination 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 if

- you are allergic (hypersensitive) to lamotrigine or to any of the ingredients of lamotrigine tablets (listed in section 6). An allergic reaction may include rash, itching, swelling of face, lips, tongue or hands/feet, or breathing difficulties.

If this applies to you, please contact your doctor and don't take Lamotrigine tablets.

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 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.

Brugada syndrome

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. Talk to your doctor, if you have this condition.

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 any of these applies to you, please tell your doctor, who may decide to lower the dose, or decide whether Lamotrigine tablets is suitable for you or not.

Important information about potentially life threatening reactions

A small number of people taking Lamotrigine get an allergic reaction or potentially serious 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 tablets.

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 tablets.

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 have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

If you are taking Lamotrigine for epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking Lamotrigine tablets. 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 are taking Lamotrigine tablets.

See a doctor as soon as possible.

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.

Other medicines and Lamotrigine tablets

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, even those not prescribed but bought/ obtained 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, Aripiprazole 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 medicines.

Some medicines interact with Lamotrigine 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 of these medicines.

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 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 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 is affecting the way your contraceptive is working.

Pregnancy and Breast-feeding

Contact your doctor if you are pregnant or might become pregnant or planning to become pregnant.

It's important that you do this because there may be an increased risk of birth defects in babies whose mothers took Lamotrigine 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.

Pregnancy may also alter the effectiveness of Lamotrigine, so your doctor may take samples of your blood to check the level of Lamotrigine, and may adjust your dose.

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.

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

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.

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 if you decide to breast feed.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Lamotrigine tablets 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 contains lactose

This medicine contains small amounts of an inactive ingredient known as Lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Lamotrigine tablets.

3. How to take Lamotrigine Tablets

Take this medicine exactly as instructed by your doctor. Check the label carefully for how much and how often to take this medicine. Check with your doctor or pharmacist if you are not sure.

How much Lamotrigine tablets 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 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 tablets than your doctor tells you to.**

The usual effective dose of Lamotrigine 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 200 mg daily.

Lamotrigine tablets are not recommended for children aged under 2 years.

How to take your dose of Lamotrigine tablets

Take your dose of Lamotrigine 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 you have taken more Lamotrigine Tablets than you should

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, you should consult the doctor or go to the nearest hospital casualty department immediately. Take this leaflet or some tablets with you so the doctor will know what medicine has been taken.

If you take too much Lamotrigine Tablets you may be more likely to have serious side effects which may be fatal. Someone who has taken too much Lamotrigine Tablets 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 tablets

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lamotrigine tablets

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

If you're taking Lamotrigine for epilepsy

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

If you're taking Lamotrigine for bipolar disorder

Lamotrigine may take some time to work, so you are unlikely to feel better straight away. If you stop taking Lamotrigine, 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.

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

4. Possible side effects

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

Potentially serious reactions: Contact your doctor immediately.

A small number of people taking lamotrigine 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, especially if the starting dose is too high or if the dose is 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*) or extended rashes with the liver, blood and other body organs involvement (DRESS).
- **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
 - 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.
- Haemophagocytic lymphohistiocytosis (HLH) (see section 2 What you need to know before you take lamotrigine).
 - Lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection

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 your doctor immediately. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamotrigine tablets. 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
- skin rash.

Common side effects

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

- feeling dizzy
- feeling sleepy or drowsy
- feeling sick (*nausea*) or being sick (*vomiting*)
- feeling agitated
- aggression or irritability
- shaking or tremors
- difficulty in sleeping (*insomnia*)
- diarrhoea
- dry mouth
- feeling tired
- pain in your back or joints, or elsewhere.

Uncommon side effects

These may affect **up to 1 in 1,00** people:

- clumsiness and lack of co-ordination (*ataxia*)
- double vision or blurred vision
- unusual hair loss or thinning (*alopecia*)

Rare side effects

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

- itchy eyes, with discharge and crusty eyelids (*conjunctivitis*)
- 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*)
- a life-threatening 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
- 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 life-threatening 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) : *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, 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*) : *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*
- 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).

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): *(see also the information at the beginning of Section 4)*

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5 How to store Lamotrigine Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste 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 tablet contains

- The **active** substance is Lamotrigine.
- The other ingredients are lactose monohydrate, microcrystalline cellulose (Avicel PH 101 & 102), povidone K30, sodium starch glycollate (Type A), magnesium stearate, ferric oxide yellow (E172), colloidal anhydrous silica and talc.*(see section 2 for Important information about some of the ingredients of Lamotrigine tablets).*

What Lamotrigine Tablet looks like and contents of the pack

Lamotrigine 25mg tablets are Light yellow to yellow coloured, capsule shaped, biconvex, uncoated tablets debossed with 'E' and '1' on either side of the scoreline on one side and breakline on the other side.

Lamotrigine 50mg tablets are Light yellow to yellow coloured, capsule shaped, biconvex, uncoated tablets debossed with 'E' and 'B' on either side of the scoreline on one side and breakline on the other side.

Lamotrigine 100mg tablets are Light yellow to yellow coloured, capsule shaped, biconvex, uncoated tablets debossed with 'E' and 'C' on either side of the scoreline on one side and breakline on the other side.

Lamotrigine 200mg tablets are Light yellow to yellow coloured, capsule shaped, biconvex, uncoated tablets debossed with 'E' and 'D' on either side of the scoreline on one side and breakline on the other side.

Lamotrigine tablets are available as blister packs in the pack sizes of 7, 14, 21, 28, 30, 56 and 100 tablets. (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

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