

Lamotrigine Accord-UK 5mg, 25mg and 100mg dispersible tablets



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 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.
- The full name of this medicine is Lamotrigine Accord-UK 5mg, 25mg and 100mg dispersible tablets, but within this leaflet it will be referred to as Lamotrigine tablets.

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
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6. Contents of the pack and other information

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

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

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

- For adults and children aged 13 years and over, Lamotrigine tablets can be used on its own or with other medicines, to treat epilepsy. Lamotrigine tablets can also be used with other medicines to treat the seizures-Gastaut with a condition called Lennox-Gastaut syndrome.
- For children aged between 2 and 12 years, Lamotrigine tablets 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 tablets 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 tablets 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 tablets works in the brain to have this effect.

2. What you need to know before you take Lamotrigine tablets:

Do not take Lamotrigine tablets if you:

- are **allergic** (hypersensitive) to lamotrigine or any of the other ingredients of Lamotrigine tablets (listed in Section 6)

If this applies to you: **Tell your doctor**, and don't take Lamotrigine tablets

If you develop a rash or the following skin symptoms, seek immediate advice from a doctor and tell them that you are taking this medicine:

- potentially life-threatening skin rashes (Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS, also known as Hypersensitivity Syndrome (HSS))) have been reported with the use of Lamotrigine tablets 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 and genitals or 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 SJS, TEN or DRESS with the use of Lamotrigine tablets, you must not be re-started on Lamotrigine tablets at any time.

Warnings and Precautions

Your doctor needs to know before you take

Lamotrigine tablets if you:

- **have problems with your kidneys**
- suffer from **liver problems**, as your doctor may need to decrease your dose
- **have ever developed a rash** when you've taken lamotrigine or other medicines for epilepsy, or if you experience a rash or sunburn after taking lamotrigine and having been exposed to sun or artificial light (e.g. solarium). Your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun (e.g. use of a sunscreen and/or to wear protective clothing)
- **are already taking medicine that contains lamotrigine**
- have **Parkinson's disease**.
- have **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.
- have **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 apply to you: **Tell your doctor**, who may decide to lower your dose, or that Lamotrigine tablets are not suitable for you.

Watch out for important symptoms

If you develop any of these symptoms after you start taking Lamotrigine tablets, **get a doctor's help straight away**:

- **an unusual skin reaction**, such as redness or rashes
- **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 your fingers turning blue
- **a sore throat** or more infections (such as colds) than usual.

These symptoms are more likely to happen during the first few months of treatment with Lamotrigine tablets, especially if you start on too high a dose or if your dose is increased too quickly, or if you're taking Lamotrigine tablets with another medicine called valproate. Children are more likely to be affected than adults.

Important information about potentially life-threatening reactions

A small number of people taking Lamotrigine tablets 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 tablets. This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested previously carrying this genetic variant (HLA-B* 1502), discuss this with your doctor before taking Lamotrigine tablets. For more information on these reactions, please read section 4 (Possible side effects).

DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

The symptoms listed above can develop into more serious problems, such as organ failure or a very severe skin condition, if they are not treated.

If you notice any of these symptoms: **See a doctor as soon as possible**. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamotrigine tablets. If you have developed SJS, TEN or DRESS with the use of Lamotrigine tablets, the treatment must not be restarted at any time.

Lamotrigine tablets should not be restarted in patients who have discontinued treatment due to aseptic meningitis. See section 4.

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).

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**.

If you're taking Lamotrigine tablets for epilepsy

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

Lamotrigine tablets **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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines or other medicines prescribed without a prescription. **It is important to tell your doctor or pharmacist if you are taking any other medicines for epilepsy at the same time as lamotrigine if you are pregnant, think you may be pregnant, or are planning to have a baby (see also the information in Section 2 on pregnancy and breastfeeding)**.

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 tablets. 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**
- **butyprone**, 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 tablets or make it more likely that you'll 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, atazanavir and ritonavir)
- **hormonal contraceptives**, such as the **Pill** (see below).

Tell your doctor if you are taking, or if you start or stop taking any of these.

Hormonal contraceptives (such as the Pill) can affect the way Lamotrigine tablets 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. If you plan to start using a hormonal contraceptive: **Talk to your doctor**, who will discuss suitable methods of contraception with you.

Lamotrigine tablets 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 tablets are affecting the way your contraceptive is working.

Pregnancy and breast feeding

• **If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.**

• **If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.**

• **You should not stop treatment without discussing it with your doctor.** This is particularly important if you have epilepsy.

• Pregnancy may alter the effectiveness of Lamotrigine tablets, so you may need blood tests and your dose of Lamotrigine tablets may be adjusted.

• Studies of women who took lamotrigine at usual doses while they were pregnant have not shown an



increased risk of physical birth abnormalities.

- The risk of physical birth abnormalities may increase when higher doses of epilepsy medicines are taken or more than one epilepsy medicine is used at the same time. Where possible, your doctor will consider using one epilepsy medicine at the lowest effective dose to control your epilepsy.

- Your doctor may advise you to take **folic acid** supplements 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 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.

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.

Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lamotrigine tablets:

Always use Lamotrigine tablets **exactly as your doctor has told you to.** Check with your doctor or pharmacist if you're not sure.

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

- your age
- whether you are taking Lamotrigine tablets with other medicines
- whether you have problems with your kidneys or liver.

Your doctor will start you on a low dose, 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 tablets for adults and children aged over 12 years is between 100mg and 400mg each day.

For children aged 2 to 12 years, the effective dose depends on their body weight - usually, it's between 1mg and 15mg for each kilogram of the child's weight, up to a maximum of 400mg daily.

How to take your dose of Lamotrigine tablets:

Take your dose of Lamotrigine tablets once or twice a day, as your doctor advises. You can take it with or without food.

Always take the full dose that your doctor has prescribed. Never take only part of a tablet.

You can take Lamotrigine tablets dispersible/chewable tablets by swallowing them whole with a little water, by chewing them, or by dissolving them in water:

If you chew the tablet:

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

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 for about a minute, until the tablet is fully dissolved.

Drink all the liquid.

— — — — — Add a little more water to the glass and drink that, to make sure you've taken all the medicine.

If you take more Lamotrigine tablets than you should

If anyone takes too many Lamotrigine tablets: **Contact a doctor or pharmacist immediately.** If possible, show them the Lamotrigine tablets packet.

Someone who has taken too many

Lamotrigine tablets 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
- QRS broadening (intraventricular conduction delay, a condition which affects the heart).

Fatal cases have been reported.

If you forget to take Lamotrigine tablets:

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

If you have missed taking a dose of Lamotrigine tablets:

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

Don't stop taking Lamotrigine tablets without advice

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

If you are taking Lamotrigine tablets for epilepsy

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

If you are taking Lamotrigine tablets for bipolar disorder

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

4. Possible side effects

Like all medicines, Lamotrigine tablets can cause side effects, but not everyone gets them.

Allergic reaction or potentially serious skin reaction: get a doctor's help straight away

A small number of people taking Lamotrigine tablets get an allergic reaction or potentially serious skin reaction, which may develop into more serious, potentially 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 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 life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) (rare, may affect up to 1 in 1,000 people), extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis) (very rare, may affect up to 1 in 10,000 people) 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) (very rare, may affect up to 1 in 10,000 people)
- 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 your fingers turning blue
- a sore throat, or more infections (such as colds) than usual
- haemophagocytic lymphohistiocytosis (HLH) (very rare, may affect up to 1 in 10,000 people) (see section 2 "What you need to know before you take lamotrigine")
- 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 - so, if you notice any of these symptoms: See a doctor as soon as possible.** Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Lamotrigine tablets

Other side effects

Very common: (affects more than 1 in 10 people):

- headache
- skin rash.

Common: (affects up to 1 in 10 people):

- aggression or irritability
- shaking or tremors
- difficulty in sleeping
- diarrhoea
- dry mouth
- feeling tired, sleepy or drowsy
- feeling dizzy
- feeling sick (nausea) or being sick (vomiting)
- agitation
- joint stiffness.

Uncommon (may affect up to 1 in 100 people):

- skin rash or sunburn after exposure to sun or artificial light (photosensitivity)
- alopecia (hair loss)
- clumsiness and lack of co-ordination (ataxia)
- double vision or blurred vision.

Rare: (affects up to 1 in 1,000 people):

- itchy eyes, with discharge and crusty eyelids (conjunctivitis)
- rapid, uncontrollable eye movements (nystagmus)
- aseptic meningitis (symptoms include sensitivity to light, rash, muscle pain, fever and stiff neck).

Very rare: (affects 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 repeated body movements and/or sounds or words (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
- changes in liver function, which will show up in blood tests, or liver failure
- changes which may show up in blood tests - including reduced numbers of red blood cells (anaemia), reduced numbers of white blood cells (leucopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), reduced numbers of all these types of cell (pancytopenia), and a disorder of the bone marrow called aplastic anaemia
- in people who already have Parkinson's disease, worsening of the symptoms.
- lupus-like reactions – pain in your back or joints, or elsewhere which may be accompanied by fever and/or general ill health

Not known (frequency cannot be estimated from the available data)

- swollen glands in the neck, armpit or groin (lymphadenopathy)
- red nodules or patches on the skin (pseudolymphoma)
- lower immunity because of lower levels of antibodies called immunoglobulins in the blood which help protect against infection (hypogammaglobulinaemia)
- nightmares
- inflammation of the kidney (tubulointerstitial nephritis) or inflammation of both the kidney and the eye (tubulointerstitial nephritis with uveitis syndrome).

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, pharmacist or nurse. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 take this medicine after the expiry date shown on the blisters, carton or bottle. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original packaging.

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 tablets contain

The active substance (the ingredient that makes the medicine work) is lamotrigine. Each tablet contains either 5mg, 25mg or 100mg of the active substance. The other ingredients are magnesium carbonate, microcrystalline cellulose, povidone, hydroxypropyl cellulose, sodium saccharin, crospovidone, guar gum, blackcurrant flavour and magnesium stearate.

What Lamotrigine tablets look like and contents of the pack

Lamotrigine 5mg tablets are white to off-white, capsule shaped, biconvex tablets (approximately 11mm long and 5.5mm wide) debossed with "U5" on one side and plain on the other side.

Lamotrigine 25mg tablets are white to off-white, round, flat-faced bevelled-edged tablets (approximately 5.5mm in diameter) debossed with "U1" on one side and plain on the other side.

Lamotrigine 100mg tablets are white to off-white, round, flat-faced bevelled-edged tablets (approximately 9mm in diameter) debossed with "U3" on one side and plain on the other side.

Available pack sizes are 28 or 56 tablets.

Marketing Authorisation Holder

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Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257.

