

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*)
- a rare skin condition, with severe blisters, and bleeding from the lips, eyes, mouth, nose and genital area (*Stevens–Johnson syndrome*).

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
- a severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (*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
- 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 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*). These symptoms usually disappear once treatment is stopped however if the symptoms continue or get worse **contact your doctor**.
- 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.

If you get side effects

→ If any of the side effects becomes severe or troublesome, or if you notice any side effects not listed in this leaflet **please tell your doctor or pharmacist**.

5. HOW TO STORE Lamotrigine

Keep Lamotrigine out of the sight and reach of children.

Do not use Lamotrigine after the expiry date shown on the blisters, carton or bottle. The expiry date refers to the last day of that month.

Lamotrigine does not require any special storage conditions.

If you have any unwanted Lamotrigine tablets, don’t dispose of them in your waste water or your household rubbish. Take them back to your pharmacist, who will dispose of them in a way that won’t harm the environment.

6. FURTHER INFORMATION

What Lamotrigine tablets contain

Each tablet contains 5 mg, 25 mg, or 100 mg of the active ingredient Lamotrigine. The other ingredients are magnesium carbonate, microcrystalline cellulose, povidone, hydroxypropyl cellulose, saccharin, crospovidone, guar gum, blackcurrant flavour and magnesium stearate.

What Lamotrigine tablets look like and contents of the pack

Lamotrigine tablets are white or almost white
The 5mg tablets are capsule-shaped with '5' marked on one side.
The 25mg & 100mg tablets are round with '25' or '100' marked on one side.
They are supplied in blister packs of 10, 14, 20, 28, 30, 42, 50, 56, 98 and 100 tablets

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder: Strandhaven Ltd T/A Somex Pharma, Ilford, Essex, IG3 8BS

Manufacturer: Actavis hf, Reykjavíkurvegur 78, IS-220 Hafnarfjörður, Iceland.

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PATIENT INFORMATION LEAFLET

Lamotrigine 5mg, 25mg & 100mg
Dispersible tablets

Read all of this leaflet carefully before you start taking this medicine.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

- What Lamotrigine is and what it is used for
- Before you take Lamotrigine
- How to take Lamotrigine
- Possible side effects
- How to store Lamotrigine
- Further information

1. WHAT LAMOTRIGINE 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 **treats epilepsy** by blocking the signals in the brain that trigger epileptic seizures (fits).

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

2. BEFORE YOU TAKE LAMOTRIGINE

Do not take Lamotrigine:

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

If this applies to you:

→ **Tell your doctor**, and don’t take Lamotrigine.

Take special care with Lamotrigine

Your doctor needs to know before you take Lamotrigine:

- if you have problems with your kidneys**
- if you have ever developed a rash** when you’ve taken lamotrigine or other medicines for 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 your dose or that Lamotrigine, is not suitable for you.

Watch out for important symptoms

If you develop any of these symptoms after you start taking Lamotrigine, **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, especially if you start on too high a dose or if your dose is increased too quickly, or if you’re taking Lamotrigine with another medicine called *valproate*. Children are more likely to be affected than adults.

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.

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 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 Lamotriginefor epilepsy

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking Lamotrigine. 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:
→ **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.

Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones — these include herbal medicines or other medicines you bought without a prescription.

If you are taking certain medicines, your doctor may need to check the dose of Lamotrigine. These include:

- **oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide**, used to treat **epilepsy**
- **lithium**, 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 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**
- **olanzapine**, used to treat **mental health problems**
- **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, or if you start or stop taking, any of these.

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 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 contracep-tive:
→ **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

→ **Talk to your doctor if you're pregnant, if you might be pregnant, or if you're planning to become pregnant.**

You should not stop treatment for your epilepsy while you're pregnant. However, there is 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 **folic 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.

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

Driving and using machines

Lamotrigine 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

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

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

The usual effective dose of Lamotrigine for adults and children aged over 12 years 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.

How to take your dose of Lamotrigine

Dispersible/chewable tablets:
Take your dose of Lamotrigine 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.

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.

You can take Lamotrigine 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 than you should

If anyone takes too much Lamotrigine:
→ **Contact a doctor or pharmacist immediately.** If possible, show them the Lamotriginepacket.

Someone who has taken too much Lamotrigine 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

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:

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

Don't stop taking Lamotrigine without advice

Take Lamotriginefor as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you are taking Lamotrigine for epilepsy

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

If you are 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.

4. POSSIBLE SIDE EFFECTS

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

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

- **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 your 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** — 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.

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.