

Lamotrigine Tablets USP 25mg/50mg/100mg Taj Pharma

(Lamotrigine)

Package Leaflet: Information for the user

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

In this leaflet

- 1 What Lamotrigine tablets are and what they are used for
- 2 Before you take Lamotrigine tablets
- 3 How to take Lamotrigine tablets
- 4 Possible side effects
- 5 How to store Lamotrigine tablets
- 6 Further information

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

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

Lamotrigine tablets **treat 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 their own or with other medicines, to treat epilepsy. Lamotrigine tablets 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 tablets can be used with other medicines, to treat the same conditions. They can be used on their own to treat a type of epilepsy called typical absence seizures.

Lamotrigine tablets also **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 tablets can be used on their own or with other medicines, to prevent the periods of depression that occur in bipolar disorder. It is not yet known how Lamotrigine tablets work in the brain to have this effect.

2. 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)
- have **liver** problems.

If these apply to you, tell your doctor, and don't take Lamotrigine tablets.

Take special care with Lamotrigine tablets

Your doctor needs to know before you take Lamotrigine tablets if you

- have problems with your **kidneys**
- have ever **developed a rash** when you've taken lamotrigine or other medicines for epilepsy
- are **already taking** medicine that contains **lamotrigine**
- have **Parkinsons disease**.

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, 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.

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.

Severe skin reactions

Potentially life-threatening skin rashes (Steven-Johnson syndrome, toxic epidermal necrolysis, DRESS) have been reported with the use of Lamotrigine, 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, you must not be re-started on lamotrigine at any time.

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

Risk of increased or severe seizures

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.

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.

A small number of people with epilepsy being treated with Lamotrigine tablets have also had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

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.

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 tablets.

These include:

- oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate or zonisamide for epilepsy
- lithium for mental health problems
- bupropion for 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 or carbamazepine for epilepsy and mental health problems
- phenytoin, primidone or phenobarbitone for epilepsy
- olanzapine or risperidone for mental health problems

- rifampicin, an antibiotic
- a combination of lopinavir, atazanavir and ritonavir used to treat Human Immunodeficiency Virus (HIV) infection
- hormonal contraceptives, such as the Pill (see below)
- orlistat used in obesity.

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 work

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 tablets. 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

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 tablets 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 tablets, so your doctor may take samples of your blood to check the level of Lamotrigine tablets, and may adjust your dose.

Talk to your doctor if you're breast feeding or planning to breast feed. 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 tablets, and will check your baby from time to time if you decide to breast feed.

Driving and using machines

If you have epilepsy, talk to your doctor about driving and using machines.

Lamotrigine tablets can cause dizziness and double vision, do not drive or operate machines if you are affected.

Important information about some of the ingredients of Lamotrigine tablets

Lamotrigine tablets contain small amounts of a sugar called lactose. If you have intolerance to lactose or any other sugars, tell your doctor, and don't take Lamotrigine tablets

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.

How much Lamotrigine to take

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.

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 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
- clumsiness and lack of co-ordination, affecting their balance
- loss of consciousness or coma.

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.

However 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 have an allergic reaction or potentially serious skin reaction, which may develop into more serious, and even life-threatening, problems if they are not treated. Symptoms of these reactions include:

- skin rashes or redness
- sore mouth or eyes
- 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
- sore throat, or more infections (such as colds) than usual
- very rarely potentially life-threatening skin rashes, Stevens-Johnson syndrome (skin condition, with severe blisters, and bleeding from the lips, eyes, mouth, nose and genital area) or Toxic epidermal necrolysis (severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin) or DRESS

In many cases these symptoms will be signs of less serious side effects. **However, 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 side effects: (affects more than 1 in 10 people):

- headache
- feeling dizzy or sleepy
- clumsiness and lack of co-ordination
- double or blurred vision
- feeling or being sick
- skin rash.

Common side effects: (affects less than 1 in 10 people):

- aggression or irritability
- rapid, uncontrollable eye movements
- shaking or tremors
- difficulty in sleeping
- diarrhoea
- dry mouth
- feeling tired
- pain in your back or joints, or elsewhere.

Rare side effects: (affects less than 1 in 1,000 people):

- itchy eyes, with discharge and crusty eyelids (conjunctivitis)

Very rare side effects: (affects less than 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, 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, reduced numbers of platelets (thrombocytopenia), reduced numbers of all these types of cell, and a disorder of the bone marrow called aplastic anaemia
- a disorder of blood clotting, which can cause unexpected bleeding or bruising
- in people who already have Parkinson's disease, worsening of the symptoms.

Other (frequency not known)

- aseptic meningitis (symptom include sensitivity to light, rash, muscle pain, fever and stiff neck), hair loss, DRESS.

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.

5. How to store Lamotrigine tablets

Keep out of the sight and reach of children.

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

Lamotrigine tablets do not require any special storage conditions.

If you have any unwanted 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

The active substance is lamotrigine.

a) Each uncoated tablet contains:

Lamotrigine USP	25mg
Excipients	q.s.

b) Each uncoated tablet contains:

Lamotrigine USP	50mg
Excipients	q.s.

c) Each uncoated tablet contains:

Lamotrigine USP	100mg
Excipients	q.s.

The other ingredients are colloidal anhydrous silica, iron oxide hydrate yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycollate and talc.

Contents of the pack

Aluminium blister packs:



Pack sizes: 7,14, 28, 30, 50, 90, 100 and 500 tablets.

Not All Packs May Be Marketed.

**7. Manufactured In India By:
TAJ PHARMACEUTICALS LTD.**

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m.

EST

E-mail: tajgroup@tajpharma.com