

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lamotrigine Torrent 25mg tablets
Lamotrigine Torrent 50mg tablets
Lamotrigine Torrent 100mg tablets
Lamotrigine Torrent 200mg tablets



lamotrigine

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

1. What Lamotrigine Torrent tablets are and what they are used for
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1. WHAT LAMOTRIGINE TORRENT 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 those 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 TORRENT TABLETS

Do not take Lamotrigine Torrent 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.

Take special care with Lamotrigine tablets

Your doctor needs to know before you take Lamotrigine tablets:

- 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 tablets are not suitable for you.

Important information about potentially serious reactions

A small number of people taking Lamotrigine tablets get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. 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 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 tablets:

→ **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 tablets 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 Torrent 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.

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.

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 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.

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 and ritonavir or 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 Torrent 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. If you are using a hormonal contraceptive, or 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.**

It's important that you do this because there may be 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 **folic 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 and may adjust your dose.

→ **Talk to your doctor if you're breast feeding or planning to breast feed.** The active ingredient of Lamotrigine tablets 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

Lamotrigine tablets can cause dizziness and double vision.

→ **Do not 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.

Important information about some of the ingredients of Lamotrigine tablets

Lamotrigine tablets contain small amounts of a sugar called **lactose**. If you have an intolerance to lactose or any other sugars:

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

3. HOW TO TAKE LAMOTRIGINE TORRENT 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 many Lamotrigine Torrent tablets 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 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 tablets for adults and children aged over 12 years is between 100 mg and 400 mg each day.

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

For children aged 2 to 12 years, the effective dose depends on their body weight — usually, it is 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 Torrent tablets

Take your dose of Lamotrigine tablets 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 are 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 Torrent tablets than you should

→ **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.

If you forget to take Lamotrigine Torrent tablets

Do not take extra tablets or a double dose to make up for a forgotten dose.

If you have missed taking a dose of Lamotrigine Torrent 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. Do not stop unless your doctor advises you to.

If you are taking Lamotrigine Torrent tablets for epilepsy

To stop taking Lamotrigine tablets, it is important that the 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 Torrent 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.

Potentially serious reactions: 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 problems if they are not treated.

These symptoms are more likely to happen during the first few months of treatment with Lamotrigine tablets, especially if the starting dose is too high or if the dose is increased too quickly, or if Lamotrigine tablets are 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*)
- **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 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 tablets.

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.

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 severe 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 or agitation
- feeling 'wobbly' or unsteady when you move about
- uncontrollable body movements (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*choreaathetosis*), or other unusual body movements such as jerking, shaking or stiffness
- a severe 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
- 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 TORRENT TABLETS

Keep Lamotrigine tablets out of the sight and reach of children.

Do not use Lamotrigine tablets 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 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 Torrent tablets contain

- The active substance is lamotrigine. Each tablet contains 25 mg, 50 mg, 100 mg or 200 mg lamotrigine.
- The other ingredients are: lactose monohydrate; microcrystalline cellulose; sodium starch glycolate; povidone; magnesium stearate; talc; colloidal silicon dioxide and iron oxide yellow.

What Lamotrigine Torrent tablets look like and contents of the pack

Lamotrigine tablets (all strengths) are yellow, round with a breaking line.

Lamotrigine tablets come in packs of 10, 28, 30, 50, 56, 90, 100 and 200 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Torrent Pharma (UK) Ltd.
Unit 4, Charlwood Court,
County Oak Way
Crawley
West Sussex. RH11 7XA
United Kingdom

This leaflet was last approved in **02/2014**.

Lamotrigine Torrent tablets

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Manufacturer

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United Kingdom



2696

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No. :
SIZE : 150 x 545 mm	Front/Back Side	CODE : 8043659-7803
REMARK : Folding Length 35 mm		DATE : 22-05-2014
SUBSTRATE :		
Activities	Department	Name
Prepared By	Pkg.Dev	Signature
Reviewed By	Pkg.Dev	Date
Reviewed By	RA	
Approved By	CQA	

This colour proof is not colour blinding. Follow Pantone shade reference for actual colour matching.

Colour Black