



# LAMOTRIGINE GENERIC HEALTH

There are reports of severe, potentially life-threatening rashes associated with Lamotrigine generic health treatment, particularly in children. Lamotrigine generic health should be discontinued at the first sign of rash unless the rash is clearly not drug related.

## What is in this leaflet

This leaflet answers some common questions about Lamotrigine generic health. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Lamotrigine generic health against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again. •

## What Lamotrigine generic health is used for

Lamotrigine generic health contain lamotrigine as the active ingredient in and belongs to a group of medicines called "anti-epileptic drugs" Anti-epileptic drugs such as Lamotrigine generic health are used to treat several conditions, including epilepsy.

Lamotrigine generic health is used for the treatment of epilepsy in patient over 2 years of age. In general, it is initially used in addition to other medicines for the treatment of epilepsy including partial or generalised seizures and Lennox-Gastaut Syndrome.

It is thought that Lamotrigine generic health works by changing the levels of

some chemicals associated with seizures.

**Ask your doctor if you have any questions about why Lamotrigine generic health has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

It is not addictive.

## Before you take Lamotrigine generic health

*When you must not take it*

**Do not take Lamotrigine generic health if you have ever had an allergic reaction to:**

- lamotrigine
- any of the ingredients listed toward the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body, rash, itching or hives on the skin.

**Do not take medicine after the expiry date (EXP) printed on the pack has passed.**

**Do not take it if the packaging is torn or shows signs of tampering.**

*Before you start to take it*

**Tell your doctor if you are taking any other medicines that contain lamotrigine.**

**Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- a history of allergy or rash to other antiepileptic drugs.
- liver or kidney disease.
- Parkinson's disease.
- If you have ever developed meningitis after taking lamotrigine

**Tell your doctor if you are pregnant or trying to become pregnant.**

Lamotrigine generic health may affect your unborn baby if you take it during pregnancy but it is still important that you control your fits while you are pregnant. Your doctor will discuss the risks and benefits of taking it during pregnancy.

It is recommended that women on antiepileptic drugs, such as Lamotrigine generic health, receive pre-pregnancy counseling with regard to the possible risk to their unborn child.

Studies have shown a decrease in the levels of folic acid during pregnancy when Lamotrigine is used. It is therefore recommended that you take a daily 5 mg folate supplement before becoming pregnant and during the first 12 weeks of your pregnancy.

**Tell your doctor if you are breast feeding or planning to breast feed.**

Lamotrigine generic health can pass into breast milk and may affect your baby.

Your doctor will discuss the risks and benefits of taking Lamotrigine generic health if you are breastfeeding.

**Do not give this medicine to anyone else even if their symptoms seem similar to yours.  
Do not take Lamotrigine generic health to treat any other complaints unless your doctor says to.**

### **Use in children**

Lamotrigine generic health is not recommended in children under 2 years of age. Children's weight should be checked and the dose reviewed as weight changes with growth occur.

### **Taking other medicines**

**Tell your doctor if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with Lamotrigine generic health. These include:

- valproate and carbamazepine, used to treat both epilepsy and mental health problems
- any form of hormonal medicine, e.g. "the pill" or HRT
- other anti-epileptic drugs, e.g. phenytoin, primidone or phenobarbitone
- OCT2 substrates such as dofetilide
- rifampicin, an antibiotic, which is used to treat infections, including tuberculosis
- medicines used to treat Human Immunodeficiency Virus (HIV) infection
- risperidone, used to treat mental health problems.

These medicines may be affected by Lamotrigine generic health or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to avoid while taking Lamotrigine generic health.

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## **How do I take Lamotrigine generic health**

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### **Using Lamotrigine generic health tablets for the first time**

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with Lamotrigine generic health. During this period you may also notice that you have slight problems with your vision. As your reactions may be slower during this period you should not operate any machinery or appliances and you should not drive a car. If any of these effects do not go away or are troublesome you should see your doctor.

**Contact your doctor immediately if you develop any skin rash such as spots or 'hives' during Lamotrigine generic health treatment.**

There are reports of severe, potentially life-threatening rashes associated with Lamotrigine generic health treatment particularly in children. Lamotrigine generic health should be discontinued at the first sign of rash unless the rash is clearly not drug related.

**If you have any questions about taking Lamotrigine generic health ask your doctor or pharmacist.**

### **How much to take**

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

- your age and weight.
- whether you are taking Lamotrigine generic health with other medications.
- whether you have any kidney or liver problems.

**Never take more Lamotrigine generic health than your doctor tells you to.**

**Do not increase the dose more quickly than you have been told.**

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.

Women taking hormonal contraceptives, such as the "the pill" may need a higher maintenance dose of Lamotrigine generic health. Your doctor will usually decrease your dose once you stop taking hormonal contraceptives.

**Tell your doctor if there are any changes in your menstrual pattern, such as breakthrough bleeding whilst on the 'pill'.**

Your doctor may need to change the dose of Lamotrigine generic health as the 'pill' may not work as effectively for contraception whilst taking it.

### **How to take it**

Lamotrigine generic health may be swallowed whole, chewed or dispersed in a small volume of water (at least enough to cover the whole tablet).

It can be taken with or without food.

Your doctor may also advise you to start or stop taking other medications, depending on what condition you are being treated for and the way you respond to treatment.

### **How long to take it**

**Do not stop taking Lamotrigine generic health, or change the dose without first checking with your doctor.**

Your doctor will advise you if you need to stop taking Lamotrigine generic health tablets and how to do this gradually over a period of two weeks.

### **If you take too much (Overdose)**

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency department at your nearest hospital, if you think you or anyone else may have taken too much Lamotrigine generic health. Do this even if there are no signs of discomfort or poisoning.**

If you take too much Lamotrigine generic health you may be more likely

to have serious side effects which may be fatal.

Symptoms of Lamotrigine generic health overdose can include rapid, uncontrollable eye movements, clumsiness and lack of coordination affecting your balance, impaired or loss of consciousness, fits or coma.

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## While you are taking Lamotrigine generic health

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### *Things you must do*

**Take Lamotrigine generic health exactly as your doctor has prescribed.**

**Contact your doctor immediately if you develop any skin rash such as spots or 'hives' during Lamotrigine generic health treatment.**

There are reports of severe, potentially life-threatening rashes associated with Lamotrigine generic health treatment, particularly in children. Lamotrigine generic health should be discontinued at the first sign of rash unless the rash is clearly not drug related.

**Tell your doctor, dentist or pharmacist who is treating you that you are taking Lamotrigine generic health, especially if you are about to be started on any new medicines. If you require a laboratory test, tell your doctor or hospital that you are taking this medicine.**

Lamotrigine generic health may interfere with some laboratory tests to detect other drugs.

**Talk to your doctor as soon as possible if you are pregnant or if you are planning to become pregnant.**

Your doctor will discuss the risks and benefits of taking Lamotrigine generic health during pregnancy.

**Talk to your doctor if you are breast feeding or planning to breast feed.**

Lamotrigine generic health can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you are taking it.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.**

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

### *Things you must not do*

**Do not stop taking Lamotrigine generic health OR change the dose without first checking with your doctor.**

If you stop taking Lamotrigine generic health suddenly your epilepsy may come back or become worse. This is known as "rebound seizures". Your doctor will advise you if you need to stop taking Lamotrigine generic health and how to do this gradually over about 2 weeks.

**Do not take a double dose to make up for any that you may have missed.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Lamotrigine generic health affects you.**

Make sure you know how you react to Lamotrigine generic health before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or lightheadedness may be worse.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling dizzy or sleepy.

**Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you or someone you know has any suicidal thoughts or other mental/mood changes.**

All mentions of suicide or violence must be taken seriously. Families and caregivers of children and adolescents who are taking Lamotrigine generic

health should be especially watchful for any changing behaviour. Anti-epileptic medicines such as Lamotrigine generic health may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

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## Side effects

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**Tell your doctor as soon as possible if you do not feel well while you are taking Lamotrigine generic health.**

All medicines can have side-effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The most commonly reported side effects of Lamotrigine generic health are:

- dizziness
- movement problems such as tics, unsteadiness and jerkiness
- skin rash
- headache
- nausea
- vomiting
- feeling drowsy or tired
- blurred or double vision
- rapid, uncontrollable eye movements
- tremor
- trouble sleeping
- feeling sleepy
- loss of memory
- hallucinations, confusion
- irritability/aggression or agitation
- liver problems
- diarrhoea
- dry mouth
- respiratory or lung problems
- depression
- increased activity in children
- joint, back or stomach pain

In general these side effects usually happen only during the first few weeks of treatment with Lamotrigine generic health.

**Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you or someone you know has any suicidal thoughts or other mental/mood changes whilst taking Lamotrigine generic health tablets.**

All mentions of suicide or violence must be taken seriously. Families and caregivers of children and adolescents who are taking Lamotrigine generic health should be especially watchful for any changing behaviour. Anti-epileptic medicines such as Lamotrigine generic health may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

### Potentially serious skin reaction

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

These symptoms are more likely to happen during the first few months of treatment with Lamotrigine generic health, especially if the dose is too high or if the dose is increased too quickly, or if Lamotrigine generic health is taken with a medicine called valproate. Serious skin reactions are more common in children. Symptoms of these serious allergic reactions include

- any skin reaction (eg. rash or 'hives')
- swelling of the face lips or tongue
- Sore mouth or sore eyes
- fever
- swollen glands
- wheezing, difficulty in breathing.

**Tell your doctor immediately if you notice any of the above symptoms.**

### Liver and blood problems

**Tell your doctor if you notice any of these symptoms:**

- drowsiness
- itching
- abdominal pain or tenderness
- feeling very tired
- easy bruising or unusual bleeding a sore throat, or more infections such as a cold, than usual
- yellow skin (jaundice).

Your doctor may decide to carry out tests on your liver, kidneys or blood and may tell you to stop taking Lamotrigine generic health if you experience these rare symptoms.

**Tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure.**

You may need urgent medical attention or hospitalisation. Serious side effects are rare.

**Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

Other side effects not listed above may also occur in some people.

**Do not be alarmed by this list of possible side-effects.**

You may not experience any of them.

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## After taking Lamotrigine generic health

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### Storage

**Keep Lamotrigine generic health where children cannot reach them**

A locked cupboard at least one- and-a-half metres above the ground is a good place to store medicines.

**Keep Lamotrigine generic health in a cool dry place, protect from light, where the temperature stays below 25°C.**

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## Product description

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**What Lamotrigine generic health looks like**

Lamotrigine generic health dispersible tablets come in 4 different strengths.

Lamotrigine generic health 25 are white to off white, round, flat faced bevelled edge tablets, plain on both sides

Lamotrigine generic health 50 are white to off white, round, flat faced bevelled edge tablets, plain on both sides

Lamotrigine generic health 100 are white to off white, round, flat faced bevelled edge tablets, plain on both sides

Lamotrigine generic health 200 are white to off white, round, flat faced bevelled edge tablets, plain on both sides

All strengths of Lamotrigine generic health are available in packs of 56 tablets

### Ingredients

#### Active ingredient:

Each Lamotrigine generic health tablet contains either 25 mg, 50 mg, 100 mg or 200 mg of lamotrigine

#### Inactive ingredients:

Each Lamotrigine generic health tablet also contains:  
crospovidone  
povidone K-30,  
mannitol  
microcrystalline cellulose  
colloidal anhydrous silica  
aspartame,  
croscarmellose sodium,  
magnesium stearate  
trusil blackcurrant flavour.

Lamotrigine generic health does not contain gluten.

Lamotrigine generic health does not contain lactose.

### Supplier

Lamotrigine generic health is supplied by:

Generic Health Pty Ltd  
Level 1  
1102 Toorak Road  
Camberwell VIC 3124

The information provided applies only to Lamotrigine generic health.

### Australian Registration Numbers:

Lamotrigine generic health 25 mg:  
AUST R 129735  
Lamotrigine generic health 50 mg:  
AUST R 129758  
Lamotrigine generic health 100 mg:  
AUST R 129761  
Lamotrigine generic health 200 mg:  
AUST R 129762

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