

LAMOTRIGINE GENERIC HEALTH

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take Lamotrigine generic health. 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. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking Lamotrigine generic health against the risks this medicine could 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 is used for the treatment of epilepsy in adults and children. Lamotrigine (the active ingredient in Lamotrigine generic health) belongs to a group of medicines called "anti-epileptic drugs"

Usually Lamotrigine generic health is initially used in addition to other medicines for the treatment of epilepsy. Lamotrigine generic health is used in partial or generalised seizures including Lennox-Gastaut Syndrome.

It is thought that Lamotrigine generic health works by changing the levels of some chemicals associated with seizures.

Your doctor may have prescribed Lamotrigine generic health for another reason.

Lamotrigine generic health is not addictive.

Before you take Lamotrigine generic health

Do not take if:

You must not take Lamotrigine generic health if:

- you have ever had an allergic reaction to Lamotrigine generic health (See "Side-Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering

Tell your doctor if:

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you have a history of allergy or rash to other antiepileptic drugs.
- you are suffering, or have ever suffered, from any liver or kidney disorders.
- you are taking any other medicines. This is particularly important for sodium valproate ("Epilim", "Valpro").
- you are taking any form of hormonal contraceptive (e.g. "the pill") or HRT, other anti-epileptic drugs (eg carbamazepine or phenobarbitone) or medicines you buy without a prescription.
- you have Parkinson's disease.
- you are breastfeeding, 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.

It is recommended that women on antiepileptic drugs, such as Lamotrigine generic health, receive pre-pregnancy

counseling with regard to the risk on their unborn child.

There is not enough information available on the use of Lamotrigine generic health during pregnancy to determine whether or not it is safe.

Lamotrigine generic health is thought to pass into breast milk.

Your doctor will discuss the risks and benefits of using Lamotrigine generic health if you are pregnant or breastfeeding, including the risk to mother and foetus of uncontrolled epilepsy, when deciding on treatment options.

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

How do I take Lamotrigine generic health

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.

If you develop any skin rash (eg spots or 'hives') during Lamotrigine generic health treatment contact your doctor immediately.

There are reports of skin rash associated with Lamotrigine generic health treatment. Some of these may be serious and cause severe illness.

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

How much to take

Take Lamotrigine generic health as directed by your doctor or pharmacist. Never change the dose yourself. Do not increase the dose more quickly than you have been told.

Your doctor and pharmacist will be able to tell you:

- how many tablets to take at each dose.
- how many doses to take each day.
- when to take each of your doses.

The label on the container that the tablets were supplied in will give the same information. If there is something that you do not understand ask either your doctor or pharmacist. It is usual for the dose of Lamotrigine generic health to start at quite a low level and be slowly increased during the first few weeks of treatment. The doses that your doctor prescribes will generally depend on any other antiepileptic medications you are taking for the treatment of epilepsy and your response to Lamotrigine generic health.

If you start or stop taking hormonal contraceptives (eg "the pill") while taking Lamotrigine generic health your doctor may need to adjust the dose of Lamotrigine generic health depending on how well your condition is being treated.

You should tell your doctor if there are any changes in your menstrual pattern, such as breakthrough bleeding.

Your doctor may need to change the dose of Lamotrigine generic health during your pregnancy.

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).

How long to take it for

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

Use in children Epilepsy:

Children's weight should be checked and the dose reviewed as weight changes occur.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre 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, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

In Australia call 13 11 26 for Poisons Information Centers. Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

If too much Lamotrigine generic health has been taken it is likely that the following symptoms will be experienced:

- nausea
- vomiting, tiredness/drowsiness and problems with eyesight.

While you are taking Lamotrigine generic health

Your doctor or pharmacist will be able to tell you whether there are any special instructions while you are taking Lamotrigine generic health.

Things you must do

If you develop any skin rash (eg spots or 'hives') during Lamotrigine generic health treatment contact your doctor immediately.

There are reports of skin rash associated with Lamotrigine generic health treatment. Some of these may be serious and cause severe illness.

Tell your doctor or pharmacist that you are taking Lamotrigine generic health if you are about to be started on any new medicines.

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

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

Do not take a double dose to make up for the one you have missed.

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 just because you feel better.

Epilepsy

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.

If you are unsure whether you should stop taking Lamotrigine generic health talk to your doctor or pharmacist.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Lamotrigine generic health to treat any other complaints unless your doctor says to.

Things to be careful of

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

As with other anticonvulsant medicines for the treatment of epilepsy Lamotrigine generic health may cause dizziness and drowsiness in some people, and affect alertness.

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.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Lamotrigine generic health, even if the problem is not listed below.

Like other medicines, Lamotrigine generic health can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side effects are:

- dizziness/unsteadiness
- headache
- drowsiness
- feeling sick, also called nausea
- vomiting
- feeling weak
- double vision
- blurred vision
- tremor
- trouble sleeping
- loss of memory
- confusion
- irritability/aggression
- agitation
- increased activity in children
- joint or back pain

In general these side effects usually happen only during the first few weeks of treatment with Lamotrigine generic health. If any of these side effects persist, or are troublesome, see your doctor.

Anti-epileptic medicines are used to treat several conditions, including epilepsy and bipolar disorder. Information from a large number of

studies in patients being treated with anti-epileptic medicines such as Lamitor DT has shown a small number of reports of suicidal behaviour (including suicidal thoughts and suicide attempts).

Tell your doctor immediately if you experience any of the following:

- Suicidal thoughts
- Suicidal attempts

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

Tell your doctor immediately if you notice any of the following:

- Any skin reaction (eg. rash or 'hives').
- Swelling of the face lips or tongue
- Sore mouth or sore eyes.
- A high temperature (fever).
- Swollen glands.
- Drowsiness.
- Easy bruising or unusual bleeding.
- Yellow skin (jaundice).

These are all very serious side effects and you may need urgent medical attention or hospitalisation.

Serious side effects are rare.

Another rare side effect is "Lupus- like reactions" which may present as a collection of symptoms consisting of fever, pain in the joints and general ill-health.

If you think you are having an allergic reaction to Lamotrigine generic health, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident and Emergency department at your nearest hospital.

Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

Tell your doctor if you are female and your menstrual periods change.

This is not a complete list of all possible side-effects. Others may occur in some

people and there may be some side-effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list. Do not be alarmed by this list of possible side-effects. You may not experience any of them.

How do I store Lamotrigine generic health?

Keep Lamotrigine generic health where children cannot reach them such as in a locked cupboard.

Keep Lamotrigine generic health in the container that they were supplied in until time to take them.

Store Lamotrigine generic health below 25°C. Protect from light and moisture.

Do not leave in a car, on a window sill or in the bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

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 face beveled edge tablets, plain on both sides

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

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

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

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

Ingredients

The active ingredient in Lamotrigine generic health is lamotrigine.

Australian Registration Numbers:

Each Lamotrigine generic health tablet contains:

25 mg lamotrigine (Lamotrigine generic health 25 mg)

50 mg lamotrigine (Lamotrigine generic health 50 mg)

100 mg lamotrigine (Lamotrigine generic health 100 mg)

200 mg lamotrigine (Lamotrigine generic health 200 mg)

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

This leaflet was prepared in August 2009.

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
Suite 1, Level 1
1175 Toorak Road
Camberwell VIC 3124

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

The information provided applies only to Lamotrigine generic health.