

Sandoz® Lamotrigine

lamotrigine tablets

Consumer Medicine Information

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

What is in this leaflet?

Please read this leaflet carefully before you start taking Sandoz Lamotrigine tablets.

This leaflet answers some common questions about Sandoz Lamotrigine tablets. 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 risks of you taking Sandoz Lamotrigine tablets against the benefits this medicine is expected to 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 Sandoz Lamotrigine tablets are used for?

Lamotrigine (the active ingredient in Sandoz Lamotrigine tablets) belongs to a group of medicines called "anti-epileptic drugs".

Sandoz Lamotrigine tablets are used for the treatment of epilepsy in adults and children, over 12 years of age. Sandoz Lamotrigine tablets are initially used in addition to other medicines for the treatment of epilepsy. Sandoz Lamotrigine is also used in partial or generalized seizures including tonic-clonic seizures and seizures associated with Lennox-Gastaut Syndrome.

An epileptic seizure, fit or turn results when abnormal electrical impulses occur in nerve cells in the brain.

These abnormal electrical impulses are believed to be due to altered levels of some chemicals in the brain.

It is thought that Sandoz Lamotrigine tablets work by changing the levels of some of the chemicals associated with seizures.

Your doctor may have prescribed Sandoz Lamotrigine tablets for another reason.

Ask your doctor if you have any questions about why Sandoz Lamotrigine tablets have been prescribed for you.

There is no evidence that Sandoz Lamotrigine tablets are addictive.

When you must NOT take Sandoz Lamotrigine tablets

Do not take Sandoz Lamotrigine tablets if you have ever had an allergic reaction to lamotrigine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

Do not take Sandoz Lamotrigine tablets after the expiry date printed on the pack.

If you take Sandoz Lamotrigine tablets after the expiry date has passed, they may not work as well.

Do not take Sandoz Lamotrigine tablets if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be taking Sandoz Lamotrigine tablets, talk to your doctor.

Before you start taking Sandoz Lamotrigine tablets

You must tell your doctor if you are pregnant or trying to become pregnant.

Sandoz Lamotrigine 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 Sandoz Lamotrigine during pregnancy and help you decide whether or not you should take Sandoz Lamotrigine tablet.

It is recommended that women on antiepileptic medicines, such as Sandoz Lamotrigine, receive pre-pregnancy counselling with regard to the risk on their unborn child.

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

You must tell your doctor if you are breastfeeding or wish to breastfeed.

Sandoz Lamotrigine is thought to pass into breast milk.

Your doctor will discuss the risks and benefits of using Sandoz Lamotrigine tablets if you are breastfeeding.

You must also 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 medicines.
- You are suffering, or have ever suffered, from any liver or kidney disorders.
- You have Parkinson's disease.
- You are taking any other medicines for epilepsy. This is particularly important for sodium valproate ("Epilim" or "Valpro"), carbamazepine ("Tegreto!"), phenobarbitone or primidone ("Mysoline").
- You are taking oral contraceptives (birth control pills) or other female hormone therapy (e.g. hormone replacement therapy [HRT]).
- You are taking rifampicin ("Rimycin" or "Rifadin"), a medicine used to treat bacterial infections.
- You are taking any other medicines that you buy with or without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking Sandoz Lamotrigine tablets with other medicines.

Your doctor will have a complete list of the medicines that may cause problems when taken with Sandoz Lamotrigine tablets.

Make sure that your doctor is aware of any of the above before you start taking Sandoz Lamotrigine tablets.

How to take Sandoz Lamotrigine tablets

Using Sandoz Lamotrigine Tablets for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with Sandoz Lamotrigine tablets. During this period you may also notice that you have slight problems with your vision such as blurred or double 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 (e.g. spots or 'hives') during Sandoz Lamotrigine treatment contact your doctor immediately.

There have been reports of life-threatening skin rash associated with Sandoz Lamotrigine treatment, particularly in children. Sandoz Lamotrigine should be discontinued at the first sign of rash unless the rash is clearly not drug related

If you have any questions about taking Sandoz Lamotrigine tablets ask your doctor or pharmacist.

How much to take

Take Sandoz Lamotrigine tablets 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 Sandoz Lamotrigine tablets 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 anti-epileptic medications you are taking, and your response to Sandoz Lamotrigine tablets.

If you are about to start or stop taking contraceptive pills while taking Sandoz Lamotrigine tablets, your doctor may need to adjust the dose of Sandoz Lamotrigine 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 Sandoz Lamotrigine during your pregnancy.

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

If you have any questions about the dose that you have been prescribed you should ask your doctor or pharmacist.

How to take it

Sandoz Lamotrigine tablets may be swallowed whole or dispersed in a small volume of water (at least enough to cover the whole tablet).

Sandoz Lamotrigine tablets are not chewable tablets.

If you have any questions about how to take Sandoz Lamotrigine tablets ask your doctor or pharmacist.

How long to take it for

Continue taking Sandoz Lamotrigine tablets for as long as your doctor tells you to. Sandoz Lamotrigine tablet helps control your condition but does not cure it. Therefore you must take your medicine every day, even if you feel well.

If you forget to take Sandoz Lamotrigine tablets

If you have forgotten to take a dose of Sandoz Lamotrigine tablet, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for a dose that you missed. If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately contact your doctor or the Australian Poisons Information Centre (13 11 26) for advice, or go to Accident or Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many Sandoz Lamotrigine tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

If too many Sandoz Lamotrigine tablets have been taken it is likely that the following symptoms will be experienced: nausea, vomiting, tiredness/drowsiness and problems with eyesight, twitching, impaired consciousness and coma.

While you are taking Sandoz Lamotrigine tablets

Your doctor or pharmacist will be able to tell you whether there are any special instructions you should be told of while you are taking Sandoz Lamotrigine tablets.

Things you must do

If you develop any skin rash (e.g. spots or hives) during Sandoz Lamotrigine treatment contact your doctor immediately.

There have been reports of life-threatening skin rash associated with Pharmacor Lamotrigine treatment, particularly in children. Sandoz Lamotrigine should be discontinued at the first sign of rash unless the rash is clearly not drug related.

Tell your doctor or pharmacist that you are taking Sandoz Lamotrigine tablets 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.

Sandoz Lamotrigine tablets may interfere with some laboratory tests to detect other drugs.

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 prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking Sandoz Lamotrigine tablets just because you feel better.

If you stop taking Sandoz Lamotrigine tablets 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 Sandoz Lamotrigine tablets and how.

If you are unsure whether you should stop taking Sandoz Lamotrigine tablets 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 Sandoz Lamotrigine tablets to treat any other complaints unless your doctor says you should.

Things to be careful of

Be careful driving or operating machinery until you know how Sandoz Lamotrigine tablets affect you.

As with other medicines for the treatment of epilepsy, Sandoz Lamotrigine may cause dizziness and drowsiness in some people and affect alertness. Make sure you know how you react to Sandoz Lamotrigine before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If these occur, do not drive.

If you drink alcohol, dizziness or light-headedness 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 Sandoz Lamotrigine should be especially watchful for any changing behaviour. Anti-epileptic medicines such as Sandoz Lamotrigine may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Sandoz Lamotrigine tablets, even if you are not sure the problems are connected with the medicine, or are not listed in this leaflet.

Like other medicines, Sandoz Lamotrigine tablets 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
- skin rash
- dry mouth
- headache
- drowsiness
- diarrhoea
- feeling sick (nausea), vomiting
- feeling weak

- movement problems such as tics, unsteadiness, jerkiness and tremor (shakiness)
- back pain or joint pain
- stomach pain
- liver problems
- double vision, blurred vision
- rapid, uncontrollable eye movements
- trouble sleeping
- hallucinations
- confusion
- loss of memory
- depression
- irritability/aggression
- agitation
- increased activity in children

Some people may have changes in their blood count, which may make them feel tired, short of breath and more susceptible to infections. They may also bleed or bruise very easily or have mouth ulcers or a sore throat.

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

Ask your doctor or pharmacist to answer any questions you may have.

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

- Suicidal thoughts
- Suicide attempts
- Depression
- Unusual changes in mood or behavior.

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

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

If you think you are having an allergic (hypersensitivity) reaction to Sandoz Lamotrigine tablets, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident or Emergency department at your nearest hospital. Symptoms usually include some or all of the following:

Potentially serious skin reaction.

A small number of people taking Pharmacor Lamotrigine 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 Sandoz Lamotrigine, especially if the dose is too high or if the dose is increased too quickly, or if Sandoz Lamotrigine 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, e.g. rash or 'hives'
- wheezing, difficulty in breathing
- swelling of the face, lips or tongue
- sore mouth or sore eyes
- fever

- swollen glands.

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 Sandoz Lamotrigine if you experience these rare symptoms.

If you are taking Sandoz Lamotrigine for epilepsy, 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.

If you are a female, tell your doctor if your menstrual periods change.

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.

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not listed here.

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.

Storage

Keep Sandoz Lamotrigine tablets where young 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 your tablets in the container that they were supplied in.

The container has been designed to help protect the tablets. If you take the tablets out of the pack they may not keep well.

Keep Sandoz Lamotrigine tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store Sandoz Lamotrigine tablets, or any other medicine, in a bathroom or near a sink.

Do not leave Sandoz Lamotrigine tablets in the car or on window sills as heat and dampness may affect the tablets.

After taking Sandoz Lamotrigine tablets

Disposal

If your doctor tells you to stop taking Sandoz Lamotrigine tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What Sandoz Lamotrigine tablets look like

Sandoz Lamotrigine tablets come in 4 different strengths.

Sandoz Lamotrigine 25mg tablets are white, round, circular tablets, with 25 debossed on one side and breakline on the other. Aust R 106985.

Sandoz Lamotrigine 50mg tablets are white, round circular tablets, with 50 debossed on one side and a breakline on the other. Aust R 106986.

Sandoz Lamotrigine 100mg tablets are white, round circular tablets, with 100 debossed on one side and a breakline on the other. Aust R 106987.

Sandoz Lamotrigine 200 mg tablets are white coloured, capsule shaped biconvex tablets, with 200 debossed on one side and plain on the other. Aust R 106988.

Ingredients

Active ingredients:

- Sandoz Lamotrigine 25 mg - 25 mg lamotrigine
- Sandoz Lamotrigine 50 mg - 50 mg lamotrigine
- Sandoz Lamotrigine 100 mg - 100 mg lamotrigine
- Sandoz Lamotrigine 200 mg - 200 mg lamotrigine

Inactive ingredients

- Lactose monohydrate
- maize starch
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate.

Sandoz Lamotrigine tablets do not contain gluten, crustacea, soya, fish, egg or tree nuts.

Supplier/Distributor

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road,
 Macquarie Park NSW 2113
 Australia
 Tel: 1800 726 369

This leaflet was prepared in September 2017.

Australian Register Number(s)

25 mg tablets: AUST R 291469 (blisters)

50 mg tablets: AUST R 291470 (blisters)

100 mg tablets: AUST R 291471 (blisters)

200 mg tablets: AUST R 291472 (blisters)

Further Information

Do not throw this leaflet away. You may need to read it again.