

SANDOZ LAMOTRIGINE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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.

1. Why am I using SANDOZ LAMOTRIGINE?

SANDOZ LAMOTRIGINE contain Lamotrigine as the active ingredient. SANDOZ LAMOTRIGINE are used to treat several conditions, including epilepsy and bipolar disorder.

For more information, see Section [1. Why am I using SANDOZ LAMOTRIGINE?](#) in the full CMI.

2. What should I know before I use SANDOZ LAMOTRIGINE?

Do not use if you have ever had an allergic reaction to lamotrigine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions take any other medicine, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SANDOZ LAMOTRIGINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with lamotrigine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SANDOZ LAMOTRIGINE?

- 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.

More instructions can be found in Section [4. How do I use SANDOZ LAMOTRIGINE?](#) in the full CMI.

5. What should I know while using SANDOZ LAMOTRIGINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist when you visit that you are using SANDOZ LAMOTRIGINE.• Contact your doctor immediately if you develop any skin rash such as spots or 'hives' during SANDOZ LAMOTRIGINE treatment.
Things you should not do	<ul style="list-style-type: none">• For epilepsy patients, do not stop taking SANDOZ LAMOTRIGINE or change the dose without first checking with your doctor.• Do not take a double dose to make up for any that you may have missed.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• Store SANDOZ LAMOTRIGINE tablets in a cool dry place where the temperature stays below 25°C.• Keep your tablets in the bottle until it is time to take them. If you take the capsules out of the bottle they may not keep as well.

For more information, see Section [5. What should I know while using SANDOZ LAMOTRIGINE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, movement problems, tremors, skin rash, headache, nausea, vomiting, feeling drowsy or tired, blurred or double vision, rapid, uncontrollable eye movements, trouble sleeping, feeling sleepy, irritability, aggression or agitation, hallucinations, confusion, increased activity in children, joint, back or stomach pain, respiratory or lung problems, depression, loss of memory, liver problems, diarrhoea, dry mouth.

Serious side effects include serious allergic reactions, liver and blood problems.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI

SANDOZ LAMOTRIGINE

Lamotrigine 25 mg, 50 mg, 100 mg, 200 mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using SANDOZ LAMOTRIGINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SANDOZ LAMOTRIGINE.**

Where to find information in this leaflet:

- [1. Why am I using SANDOZ LAMOTRIGINE?](#)
- [2. What should I know before I use SANDOZ LAMOTRIGINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SANDOZ LAMOTRIGINE?](#)
- [5. What should I know while using SANDOZ LAMOTRIGINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SANDOZ LAMOTRIGINE?

SANDOZ LAMOTRIGINE contain Lamotrigine as the active ingredient and belongs to a group of medicines called "anti-epileptic drugs".

Anti-epileptic drugs such as SANDOZ LAMOTRIGINE are used to treat several conditions, including epilepsy and bipolar disorder.

It is used for the treatment of epilepsy in patients over 2 years of age. In general, it is initially used in addition to other medicines for the treatment of epilepsy including partial or generalized seizures and Lennox-Gastaut Syndrome. It is thought that this medicine works by changing the levels of some chemicals associated with seizures.

Sandoz Lamotrigine is also used to help prevent depression in adults over 18 years of age with bipolar disorder.

Ask your doctor if you have any questions about why SANDOZ LAMOTRIGINE tablets 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.

2. What should I know before I use SANDOZ LAMOTRIGINE

Warnings

Do not use SANDOZ LAMOTRIGINE if:

- you are allergic to lamotrigine, or any of the ingredients listed at 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

Always check the ingredients to make sure you can use this medicine.

- this medicine after the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are taking any other medicines that contain lamotrigine.
- are allergic to any other medicines or any foods, dyes or preservatives.
- have or have had any of the following medical conditions:
 - a history of allergy or rash to other anti-epileptic drugs
 - liver or kidney disease
 - Parkinson's disease
 - if you have ever developed meningitis after taking lamotrigine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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.

It is recommended that women on anti-epileptic drugs, such as SANDOZ LAMOTRIGINE, receive pre-pregnancy counselling with regard to the possible risk to their unborn child.

Studies have shown a decrease in the levels of folic acid during pregnancy when SANDOZ LAMOTRIGINE is also 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

SANDOZ LAMOTRIGINE can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking SANDOZ LAMOTRIGINE if you are breast feeding.

Use in Children

Epilepsy: SANDOZ LAMOTRIGINE 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.

Bipolar: Lamotrigine is not recommended in children and adolescents under 18 years of age.

3. What if I am taking other medicines?

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

Some medicines may interfere with SANDOZ LAMOTRIGINE and affect how it works.

- 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 SANDOZ LAMOTRIGINE 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SANDOZ LAMOTRIGINE.

4. How do I use SANDOZ LAMOTRIGINE?

How to take

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. As your reactions may be slower during this period you should not operate any machinery or drive a car. If any of these effects do not go away or are troublesome you should see your doctor.

If you have any questions about taking SANDOZ LAMOTRIGINE tablets ask your doctor or pharmacist.

How much to take

It may take a while to find the best dose of SANDOZ LAMOTRIGINE for you. The dose you take will depend on:

- your age and weight
- whether you are taking SANDOZ LAMOTRIGINE with other medications
- whether you have any kidney or liver problems.
- Never take more SANDOZ LAMOTRIGINE 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 birth control 'pill' may need a higher maintenance dose of SANDOZ LAMOTRIGINE. 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 adjust the dose of SANDOZ LAMOTRIGINE as the 'pill' may not work as effectively for contraception whilst taking it.

When to take SANDOZ LAMOTRIGINE

- Talk to your doctor or pharmacist to work out when it is best for you to take your doses of SANDOZ LAMOTRIGINE.

How to take SANDOZ LAMOTRIGINE

- 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.
- 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

For epilepsy patients, do not stop taking SANDOZ LAMOTRIGINE or change the dose without first checking with your doctor.

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

If you forget to use SANDOZ LAMOTRIGINE

SANDOZ LAMOTRIGINE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much SANDOZ LAMOTRIGINE

If you take too much Sandoz Lamotrigine you may be more likely to have serious side effects which may be fatal.

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

If you think that you have used too much SANDOZ LAMOTRIGINE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SANDOZ LAMOTRIGINE?

Things you should do

Take SANDOZ LAMOTRIGINE exactly as your doctor has prescribed.

Contact your doctor immediately if you develop any skin rash such as spots or 'hives' during SANDOZ LAMOTRIGINE treatment.

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.

Contact your doctor if you experience a rash or sunburn after taking Lamotrigine and having been exposed to sun or artificial light, e.g. solarium.

Your doctor will check your treatment and may advise you to avoid sunlight or protect yourself against the sun, e.g. use of a sunscreen and/or to wear protective clothing.

Tell any other doctor, dentist or pharmacist who is treating you that you are taking SANDOZ LAMOTRIGINE,

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.

SANDOZ LAMOTRIGINE tablets may interfere with some laboratory tests to detect other drugs.

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 should not do

For epilepsy patients, do not stop taking SANDOZ LAMOTRIGINE or change the dose without first checking with your doctor.

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 to do this gradually over about 2 weeks.

Things to be careful of

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).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SANDOZ LAMOTRIGINE affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store SANDOZ LAMOTRIGINE tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the container until it is time to take them. If you take the tablets out of the bottle they may not keep as well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Dizziness • Movement problems such as tics, unsteadiness, jerkiness • Tremors • Skin rash • Headache • Nausea • Vomiting • Feeling drowsy or tired • Blurred or double vision • Rapid, uncontrollable eye movements • Trouble sleeping • Feeling sleepy • Irritability, aggression or agitation • Hallucinations, confusion • Increased activity in children • Joint, back or stomach pain • Respiratory or lung problems • Depression • Loss of memory • Liver problems • Diarrhoea • Dry mouth. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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

Serious side effects

Serious side effects	What to do
<p>Liver and blood disorders</p> <ul style="list-style-type: none"> • 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). • uncontrollable repeated body movements and/or sounds or words (tics). 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"> • Any skin reaction, e.g. Rash or 'hives' or red nodules or patches on the skin • Skin rash or sunburn after exposure to sun or artificial light (photosensitivity) • Wheezing, difficulty in breathing • Swelling of the face, lips or tongue • Sore mouth or sore eyes • Fever • Swollen glands. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor immediately, or go to 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 SANDOZ LAMOTRIGINE tablets.

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).

Potentially serious skin reaction

A small number of people taking 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.

This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested previously carrying this genetic variant (HLA-B* 1502), discuss this with your doctor before taking SANDOZ LAMOTRIGINE.

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

Potentially serious aseptic meningitis

Lamotrigine increases the risk of developing aseptic meningitis, which is a serious inflammation of the protective membrane that covers the brain and spinal cord.

Many of the side effects already listed are symptoms of this condition, as well as light sensitivity, stiff neck, muscle pains and chills.

Potentially serious / life threatening arrhythmia

If you have had a fast heartbeat, heart failure, or other heart problems, you should not take lamotrigine. This drug may cause you to have an abnormal heartbeat, which could lead to sudden death. Symptoms include a fast, slow, or pounding heartbeat, shortness of breath, chest pain, and feeling lightheaded.

Tell your doctor if you notice any of these symptoms.

If you are taking 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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SANDOZ LAMOTRIGINE contains

Active ingredient (main ingredient)	Lamotrigine
Other ingredients (inactive ingredients)	lactose, maize starch, microcrystalline cellulose, sodium starch glycollate and magnesium stearate.
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What SANDOZ LAMOTRIGINE Tablet looks like

SANDOZ LAMOTRIGINE Tablets come in four different strengths:

- **25 mg tablets**–
white, round, circular tablets, with 25 debossed on one side and breakline on the other. Aust R 291469.
- **50 mg tablets**–
white, round circular tablets, with 50 debossed on one side and a breakline on the other. Aust R 291470.
- **100 mg tablets**–
white, round circular tablets, with 100 debossed on one side and a breakline on the other. Aust R 291471.
- **200 mg tablets**
white coloured, capsule shaped biconvex tablets, with 200 debossed on one side and plain on the other. Aust R 291472.

Who distributes SANDOZ LAMOTRIGINE

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