

## LAMOTRIGINE SANDOZ®

Lamotrigine dispersible/chewable tablets

### Consumer Medicine Information

**THERE ARE REPORTS OF SEVERE, POTENTIALLY LIFE-THREATENING RASHES ASSOCIATED WITH LAMOTRIGINE TREATMENT, PARTICULARLY IN CHILDREN. 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 take Lamotrigine Sandoz tablets.

This leaflet answers some common questions about Lamotrigine Sandoz 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. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the risks of you taking Lamotrigine Sandoz 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 Sandoz is used for

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

Lamotrigine Sandoz tablets are 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.

Ask your doctor if you have any questions about why Lamotrigine Sandoz 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 it

**When you must not take it:**

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

- lamotrigine
- 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.

**Do not take this medicine:**

- **after the expiry date printed on the pack has passed**
- **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 any other medicines or any foods, dyes or preservatives.**

**Tell your doctor if you 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.

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

Lamotrigine Sandoz 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 Lamotrigine Sandoz during pregnancy.

It is recommended that women on anti-epileptic drugs, such as Lamotrigine Sandoz, 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 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.

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

Lamotrigine Sandoz can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Lamotrigine Sandoz if you are breastfeeding.

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

**Do not take Lamotrigine Sandoz to treat any other complaints unless your doctor says so.**

#### Use in children

Epilepsy: Lamotrigine Sandoz 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 Sandoz. 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 Sandoz 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 Sandoz.

#### How to take it

##### Using Lamotrigine Sandoz for the first time

You may notice that you feel dizzy, tired, or unsteady in the first few weeks of treatment with Lamotrigine Sandoz. 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 Sandoz treatment.**

There are reports of severe, potentially life-threatening rashes associated with Lamotrigine Sandoz treatment, particularly in children. Lamotrigine Sandoz 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 Sandoz tablets ask your doctor or pharmacist.**

##### How much to take

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

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

**Never take more Lamotrigine Sandoz than your doctor has told 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 Lamotrigine Sandoz. 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 while on the 'pill'.** Your doctor may need to adjust the dose of Lamotrigine Sandoz as the 'pill' may not work as effectively for contraception whilst taking it.

#### *How to take it*

Lamotrigine Sandoz tablets 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*

**For epilepsy patients, do not stop taking Lamotrigine Sandoz tablets or change the dose without first checking with your doctor.**

Your doctor will advise you if you need to stop taking Lamotrigine Sandoz 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 or Emergency department at your nearest hospital if you think you or anyone else may have taken too many Lamotrigine Sandoz tablets. Do this even if there are no signs of discomfort or poisoning.**

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

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

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#### *While you are taking it*

##### *Things you must do*

**Take Lamotrigine Sandoz exactly as your doctor has prescribed.**

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

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

**Tell any other doctor, dentist or pharmacist who is treating you that you are taking Lamotrigine Sandoz, 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 Sandoz 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 Sandoz during pregnancy.

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

Lamotrigine Sandoz can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breastfeeding 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*

**For epilepsy patients, do not stop taking Lamotrigine Sandoz or change the dose without first checking with your doctor.**

If you stop taking Lamotrigine Sandoz 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 Lamotrigine Sandoz 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 Sandoz affects you.**

Make sure you know how you react to Lamotrigine Sandoz 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.

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

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#### *Side Effects*

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

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

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

The most commonly reported side effects are:

- dizziness
- movement problems such as tics, unsteadiness and 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.

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

**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 Lamotrigine Sandoz.**

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

#### *Potentially serious skin reaction.*

A small number of people taking Lamotrigine Sandoz 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 Sandoz, especially if the dose is too high or if the dose is increased too quickly, or if Lamotrigine Sandoz 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 Lamotrigine Sandoz if you experience these rare symptoms.

**If you are taking Lamotrigine Sandoz 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 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 it

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#### *Storage*

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

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half meters of the ground is a good place to store medicine.

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### Product Description

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#### *What it looks like*

##### **Lamotrigine Sandoz 25 mg:**

Lamotrigine Sandoz dispersible/chewable tablets are white to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '80' on flat side.

##### **Lamotrigine Sandoz 50 mg:**

Lamotrigine Sandoz dispersible/chewable tablets are white to off-white rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '79' on flat side.

##### **Lamotrigine Sandoz 100mg:**

Lamotrigine Sandoz dispersible/chewable tablets are white to off white rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '78' on flat side.

##### **Lamotrigine Sandoz 200mg:**

Lamotrigine Sandoz dispersible/ chewable tablets 200 mg are white to off-white rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '77' on flat side.

Available in blister packs of 56 tablets.

#### *Ingredients*

##### **Active ingredient:**

Each Lamotrigine Sandoz tablet contains either 25 mg, 50 mg, 100 mg, 200 mg of lamotrigine.

##### **Inactive ingredients:**

- Microcrystalline cellulose (PH-101)
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- Heavy magnesium carbonate
- Polacrillin potassium
- Sucralose
- Povidone

- Magnesium stearate
- Black currant flavour 501017 AP0551 (PI-ARTG No.106513).

#### *Supplier*

Sandoz Pty Ltd  
 ABN 60 075 449 553  
 54 Waterloo Road  
 Macquarie Park, NSW 2113  
 Australia  
 Tel: 1800 634 500

#### **Australian Register Numbers:**

25 mg dispersible/chewable tablet:

AUST R 187261

50 mg dispersible/chewable tablet:

AUST R 187272

100 mg dispersible/chewable tablet:

AUST R 187278

200 mg dispersible/chewable tablet:

AUST R 187254

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