

Lamotrigine AN tablets

Lamotrigine tablets

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take Lamotrigine AN.

This leaflet answers some common questions about Lamotrigine AN.

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 benefits and risks. Your doctor has weighed the risks of you taking Lamotrigine AN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Lamotrigine AN is used for

LAMOTRIGINE AN contains the active ingredient lamotrigine and is an antiepileptic drug used to treat epilepsy in adults and children.

Epilepsy is caused by a disruption in the electrical activity of the brain.

The abnormal electrical impulses occur due to altered levels of some of the chemicals in the brain.

LAMOTRIGINE AN tablets work by altering the levels of some of the chemicals causing the seizures.

LAMOTRIGINE AN is used in partial seizures that affect only one part of the brain or generalised seizures that affect the whole brain including Lennox-Gastaut Syndrome.

Lennox-Gastaut Syndrome (LGS) is a severe form of epilepsy and is characterised by several seizure types.

LAMOTRIGINE AN tablets are initially used in addition to other medicines for the treatment of epilepsy.

Your doctor may have prescribed LAMOTRIGINE AN for another reason. Ask your doctor if you have any questions about why LAMOTRIGINE AN has been prescribed for you.

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

There is no evidence that LAMOTRIGINE AN is addictive.

Before you take Lamotrigine AN

When you must not take it

Do not take Lamotrigine AN if:

- **You have an allergy to lamotrigine or any ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing, swelling of the face, lips or tongue.
- **The packaging is torn or shows signs of tampering.**
- **The expiry date on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work as well (or it may make you feel sick).

If you are not sure whether you should start taking Lamotrigine AN, talk to your doctor.

Before you take it

You must tell your doctor:

1. **If you are allergic to any other medicines, food dyes or preservatives**
2. **If you have or have ever had any other health problems/medical conditions, including:**
 - Kidney disease
 - Liver disease
3. **If you are taking any other medicines. This is particularly important for sodium valproate ('Epilim', 'Valpro', or if you are taking any form of hormonal contraceptive (e.g 'the pill') or hormone replacement therapy, other anti-epileptic drugs (e.g carbamazepine or phenobarbitone) or medicines you buy without a prescription.**

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Lamotrigine AN.

4. **If you are breastfeeding, pregnant or trying to become pregnant.** It is recommended that women on antiepileptic drugs such as Lamotrigine AN receive pre-pregnancy counselling with regards to the risk of their unborn child.

There is not enough information available on the use of Lamotrigine AN tablets during pregnancy to determine whether or not it is safe. Lamotrigine AN is thought to pass into breastmilk.

Your doctor will discuss the risks and benefits of using Lamotrigine AN tablets 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 in women treated with Lamotrigine AN. It is therefore recommended that you take a folic acid supplement, e.g 5 mg folic acid daily, before becoming pregnant and during the first 12 weeks of your pregnancy.

If you have not told your doctor about any of the above, tell them before you are given Lamotrigine AN.

How to take Lamotrigine AN

Taking Lamotrigine AN for the first time

During the first few weeks of treatment, you may experience blurred vision, dizziness, tiredness or unsteadiness when you are walking.

As your reactions may be slower during this period, you should avoid operating any machinery and appliances and you should not drive a car. If any of these effects persist for a long period of time or prove to be troublesome, you should consult your doctor.

There have been reports of skin rash associated with treatment. Some of these rashes may be serious and can cause severe illness.

If you notice the development of any skin rash (e.g hives or spots) during treatment, contact your doctor immediately.

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

How much to take

Your doctor will determine your dose and how long you will receive Lamotrigine AN.

Take Lamotrigine AN 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 your doctor or pharmacist.

It is usual for the dose of Lamotrigine AN tablets to start at quite a low level and be slowly increased during the first few weeks of treatment.

The dose prescribed by your doctor is dependent upon the other epileptic medications you are taking and your response to Lamotrigine AN.

Hormonal contraceptives: If you start or stop taking hormonal contraceptives (e.g "the pill") while taking Lamotrigine AN, your doctor may need to adjust the dose of Lamotrigine AN 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 AN during your pregnancy.

Lamotrigine AN for children is dependent upon their weight and changes to the dose must be made accordingly.

How long to take it for

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

How to take it

Lamotrigine AN tablets may be swallowed whole, chewed or dispersed in a glass of water (at least enough to cover the whole tablet).

If you forget to take it

If you have forgotten to take your dose of Lamotrigine AN tablets, contact your doctor immediately.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

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

You may need urgent medical attention. Keep telephone numbers of these places/services handy.

If you take too much Lamotrigine AN, you may have:

- Nausea
- Vomiting
- Tiredness/drowsiness
- Problems with eyesight

While you are taking Lamotrigine AN

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

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Lamotrigine AN.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Lamotrigine AN.

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

If you develop any skin rash (e.g hives or spots) while being treated with Lamotrigine AN, contact your doctor immediately. There are reports of serious skin rash with Lamotrigine that may need hospital treatment or drug withdrawal; rarely serious skin rash may cause death.

Tell your doctor if you become pregnant or are trying to become pregnant while taking Lamotrigine AN.

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 do

Do not stop taking Lamotrigine AN or change the dose because you are feeling better. Consult your doctor first.

If you stop taking Lamotrigine AN tablets abruptly, your epilepsy may worsen or even come back. This is known as rebound seizures.

Do not give Lamotrigine AN to anyone else, even if they have the same condition as you.

Do not use Lamotrigine AN to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

Lamotrigine AN may cause dizziness and drowsiness and affect alertness in some individuals. If this occurs, avoid operating machinery, driving a car or doing anything that could be dangerous.

Make sure you know how you react to Lamotrigine AN 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 consuming alcohol, dizziness or light-headedness may be worse.

Children should avoid riding a bike, climbing trees or doing anything that could be dangerous if they are feeling dizzy or sleepy.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lamotrigine AN.

Like other medicines Lamotrigine AN can cause some side effects. If they occur, most are likely to be minor and temporary.

However, some may be serious and need medical attention.

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

The common side effects are:

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

These side effects usually occur during the first few weeks of treatment. However, if any of these side effects persist, consult your doctor.

Caution is also required when treating patients with a history of allergy or rash to other antiepileptic drugs as the frequency of non-serious rash after treatment with lamotrigine was approximately three times higher in these patients than in those without such history.

Antiepileptics, such as LAMOTRIGINE AN may increase the risk of suicidal thoughts and behaviour.

If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to your nearest hospital for treatment:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts at self-harm
- Increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- fever
- any skin reactions (e.g rash or hives)
- drowsiness
- swollen glands
- sore mouth or sore eyes
- yellow skin (jaundice)
- unusual bleeding and easy bruising
- swelling of the face, lips or tongue

These are all serious side effects of Lamotrigine AN. You may need urgent medical attention.

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 any of the following happens, stop using Lamotrigine AN and tell your doctor immediately or go to casualty at your nearest hospital:

- **Life threatening allergic reactions which may include lumpy rash ("hives"), fainting, itching, difficulty breathing, swelling of the face, lips or tongue.**

These are all very serious side effects of Lamotrigine AN. If you have them, you may have had a serious allergic reaction to Lamotrigine AN. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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.

After taking Lamotrigine AN

Storage

Keep your Lamotrigine AN tablets in their original pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep the pack in a cool, dry place where the temperature stays below 25°C and away from light.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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

Product Description

What it looks like

- **Lamotrigine AN 25 mg:**
White to off-white, modified square shape, engraved with 'L' and '25' on one side, plain on the other side (AUST R 147631).
- **Lamotrigine AN 50 mg:**
White to off-white, modified square shape, engraved with 'L' and 50 on one side, plain on the other side (AUST R 147632).
- **Lamotrigine AN 100 mg:**
White to off-white, modified square shape, engraved with 'L' and '100' on one side, plain on the other side (AUST R 147633).
- **Lamotrigine AN 200 mg:**
White to off-white, modified square shape, engraved with 'L' and '200' on one side, plain on the other side (AUST R 147634).

Ingredients

Active Ingredient:

Lamotrigine

Each tablet may contain either 25 mg, 50 mg, 100 mg, or 200 mg of Lamotrigine.

Other Ingredients:

- Calcium carbonate
- Microcrystalline cellulose
- Crospovidone
- Saccharin sodium
- Colloidal anhydrous silica
- Sodium stearyl fumarate
- Sorbitol
- Maize starch
- Purified talc
- Blackcurrant flavour LN 6644 - Givaudan

Please read this leaflet carefully before you start taking Lamotrigine AN. You may wish to read again.

Name and Address of the Sponsor

Scentia Pharmaceuticals Pty Ltd

8 - 12 Ordish Road
Dandenong South,
VIC - 3175
Australia

Date of Preparation

February 2014