

APO-Lamotrigine

Lamotrigine

Consumer Medicine Information

For a copy of a large print leaflet Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about lamotrigine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,

- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Lamotrigine. It contains the active ingredient lamotrigine.

Lamotrigine belongs to a group of medicines called "anti-epileptic drugs".

It is used to treat epilepsy in adults and children aged 2 years and over.

Usually lamotrigine is used in addition to other medicines for the treatment of epilepsy. Lamotrigine is used in partial seizures (seizures that affect only one part of the brain) or generalised seizures (seizures that affect the whole brain), including Lennox-Gastaut Syndrome (a severe form of epilepsy characterised by several seizure types).

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

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

There is no evidence that this medicine is addictive.

Use in children

This medicine may be used to treat epilepsy in children 2 years of age and over.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, lamotrigine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- It has passed the expiry date (EXP) printed on the pack.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease
 - bipolar disorder
 - Parkinson's disease
 - history of allergy or rash to other antiepileptic drugs.
 - you have ever developed meningitis after taking lamotrigine.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until

you and your doctor have discussed the risks and benefits involved.

It is recommended that women on antiepileptic drugs, including lamotrigine receive pre-pregnancy counselling regarding the risk to their unborn child.

Studies have shown that lamotrigine can decrease the levels of folic acid during pregnancy. 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.

4. You are currently breastfeeding or you plan to breastfeed. Lamotrigine can pass into breast milk and may affect your baby. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines, including vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with lamotrigine. These include:

- sodium valproate ("Epilim", "Valpro"), used to treat epilepsy

- other anti-epileptic drugs including carbamazepine, phenobarbitone and primidone
- any form of hormonal contraception (e.g. "the pill") or HRT
- OCT 2 substrates such as dofetilide
- rifampicin, which is often used to treat infections including tuberculosis
- a combination of lopinavir and ritonavir, which is used to treat Human Immunodeficiency Virus (HIV) infection.
- risperidone, which is used to treat schizophrenia and bipolar disorder. You may be more likely to feel sleepy or drowsy if you take risperidone and lamotrigine together.

If you are taking any of these medicines you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with lamotrigine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

You may notice you feel dizzy, tired or unsteady in the first few weeks of treatment with lamotrigine. During this time, you may also notice 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.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

Usually your doctor will prescribe a low dose to start and gradually increase the dose during the first few weeks of treatment. The dose that your doctor prescribes will often depend on other anti-epileptic medications you are taking and your response to lamotrigine.

Hormonal Contraceptives:

If you start or stop taking hormonal contraceptives (e.g. "the pill") while taking lamotrigine, your doctor may need to adjust the dose of 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.

If you become pregnant your doctor may need to change your dose of lamotrigine or switch you to a different medicine.

Use in children

The dosage for children usually depends on their weight. Children's weight should be checked and the dose reviewed as weight changes occur.

How to take it

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

When to take it

Take this medicine at the same time each day. Taking your medicine at the same time each day will have the best effect and it will also help you remember when to take it.

This medicine can be taken with or without food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you to.

Make sure you have enough to last over weekends and holidays.

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

If you forget to take it

Contact your doctor immediately if you have forgotten to take your dose of lamotrigine. 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 to help you remember.

If you take too much (Overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

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

While you are taking this medicine

Your doctor will tell you if there are any special instructions while you are taking lamotrigine tablets.

Things you must do

If you develop any skin rash (e.g. hives or spots) while being treated with lamotrigine, contact your doctor immediately.

There have been reports of severe, potentially life-threatening skin 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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine

Lamotrigine may interfere with some laboratory tests to detect other drugs. If you require a laboratory test, tell your doctor or hospital that you are taking lamotrigine.

- you are pregnant or are planning to become pregnant.

There may be an increased risk of babies developing a cleft lip or cleft palate if lamotrigine is taken during the first few months of pregnancy.

- you are breastfeeding or are planning to breastfeed.

Lamotrigine passes into breast milk and may affect your baby.

- you are about to have any blood tests.

- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Take any other prescription or non-prescription medicines without first telling your doctor.

Do not stop taking lamotrigine or change the dose because you are feeling better.

If you stop taking lamotrigine tablets abruptly your epilepsy may worsen or come back. This is known as "rebound seizures".

Your doctor will advise you if you need to stop taking lamotrigine and, if so, how to do this safely. If you are

unsure whether you should stop taking lamotrigine talk to your doctor.

Things to be careful of

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

Lamotrigine may cause dizziness and drowsiness, and affect alertness in some people.

Make sure you know how lamotrigine affects you 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, your dizziness or light-headedness may be worse. If any of these effects do not go away or are troublesome you should see your doctor.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking lamotrigine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following.

This list includes the more common side effects. Mostly, these are mild:

- dizziness, unsteadiness
- headache
- drowsiness
- feeling sick (nausea)
- vomiting
- feeling weak
- double vision
- blurred vision
- rapid, uncontrollable eye movements
- tremor (shakiness)
- trouble sleeping
- loss of memory
- confusion
- irritability, aggression
- agitation

- increased activity in children
- joint or back pain

Other reported side effects include:

- diarrhoea
- liver problems
- tiredness or feeling sleepy
- movement problems such as tics, unsteadiness and jerkiness
- hallucinations.

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 Lamotrigine. 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 lamotrigine 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
- suicide attempts.

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 whilst taking lamotrigine.

All mentions of suicide or violence must be taken seriously. Families and caregivers of children and adolescents who are taking lamotrigine should be especially watchful for any changing behaviour. Anti-epileptic medicines such as 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.

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. 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 immediately if you notice any of the following:

- any skin reactions (e.g. rash or 'hives')
- swelling of the face, lips or tongue
- sore mouth or sore eyes
- high temperature (fever)
- swollen glands
- abdominal pain or tenderness
- drowsiness
- easy bruising or unusual bleeding

- 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 if you experience these symptoms.

If you are taking Lamotrigine for epilepsy, rarely, you may start to experience more seizures than usual. Tell your doctor as soon as possible if your seizures get worse or if you have a new type of seizure.

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 can cause symptoms such as fever, pain in the joints and general ill health.

A very rare side effect is meningitis which may present as a group of symptoms consisting of fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord.

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.

Allergic reactions

If you think you are having an allergic reaction to lamotrigine, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees Celsius.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Lamotrigine looks like

APO-Lamotrigine 25 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI2" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine 50 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI3" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine 100 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI4" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine 200 mg:

White to off-white, uncoated, circular flat bevelled tablets debossed with "LI5" on one side, plain on the other side having a characteristic fruity odour.

APO-Lamotrigine tablets are available in blister packs of 56 tablets.

Ingredients

Each tablet contains lamotrigine as the active ingredient.

It also contains the following inactive ingredients:

- calcium carbonate
- aspartame
- microcrystalline cellulose
- crospovidone
- hyprolose
- magnesium stearate
- povidone
- colloidal anhydrous silica

- purified talc
- Cal-Carb 4450PG
- maltodextrin
- mixed berries 501161 AP0551.

This medicine is gluten-free, lactose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Lamotrigine 25 mg

(blister pack): AUST R 167520.

APO-Lamotrigine 50 mg

(blister pack): AUST R 167521.

APO-Lamotrigine 100 mg

(blister pack): AUST R 167523.

APO- Lamotrigine 200 mg

(blister pack): AUST R 167524.

Sponsor

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This leaflet was prepared in:

November 2018.