

APX-LAMOTRIGINE

25 mg, 50 mg, 100 mg & 200 mg dispersible tablets

lamotrigine

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about APX-LAMOTRIGINE. 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 APX-LAMOTRIGINE tablets 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 APX-LAMOTRIGINE is used for

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

Anti-epileptic drugs such as APX-LAMOTRIGINE are used to treat epilepsy.

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.

Ask your doctor if you have any questions about why APX-LAMOTRIGINE has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take APX-LAMOTRIGINE if you are allergic to lamotrigine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take APX-LAMOTRIGINE if the expiry date (Exp.) printed on the pack has passed.

Do not take it if the packaging shows signs of tampering or the tablets do not look quite right.

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.

APX-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 it during pregnancy.

It is recommended that women on anti-epileptic drugs, such as Lamictal, 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 Lamictal 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 can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking this medicine if you are breast feeding.

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

Do not take APX-LAMOTRIGINE to treat any other complaints unless your doctor says to.

Use in children

APX-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.

Taking other medicines

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

Some medicines may interfere with APX-LAMOTRIGINE. 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 APX-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.

Your doctor can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APX-LAMOTRIGINE.

avoid sunlight or protect yourself against the sun, e.g. use of a sunscreen and/or to wear protective clothing.

Ask your doctor or pharmacist if you have any questions about taking APX-LAMOTRIGINE.

How much to take

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

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

Never take more APX-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 with 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 this medicine. 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 change the dose of APX-LAMOTRIGINE as the 'pill' may not work effectively for contraception whilst taking it.

How to take it

APX-LAMOTRIGINE 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.

How to take it

Taking APX-LAMOTRIGINE for the first time

You may notice that you feel dizzy, tired or unsteady in the first few weeks of treatment with APX-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 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 (e.g. spots or hives) during APX-LAMOTRIGINE treatment.

There are reports of severe, potentially life-threatening rashes associated with APX-LAMOTRIGINE treatment particularly in children. It 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 APX-LAMOTRIGINE and having been exposed to sun or artificial light, e.g. solarium.

Your doctor will check your treatment and may advise you to

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

Do not stop taking APX-LAMOTRIGINE or change the dose without first checking with your doctor.

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

If you take too much (overdose)

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

You may need urgent medical attention.

If you take too much APX-LAMOTRIGINE 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 it

Things you must do

Take APX-LAMOTRIGINE exactly as your doctor has prescribed.

Contact your doctor immediately if you develop any skin rash, like spots or hives, during APX-LAMOTRIGINE treatment.

There are reports of skin rash associated with APX-LAMOTRIGINE that may need hospital treatment or drug withdrawal; rarely serious skin rash may cause death. APX-LAMOTRIGINE should be discontinued at the first sign of rash unless the rash is clearly not drug related.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking APX-LAMOTRIGINE.

Tell your doctor or pharmacist that you are taking APX-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 APX-LAMOTRIGINE.

It may interfere with some laboratory tests to detect other drugs.

Tell your doctor immediately if you become pregnant or if you are planning to become pregnant. Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

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

Lamotrigine can pass into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you are taking it.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it is not working as it should and change your dosage unnecessarily.

Things you must not do

Do not stop taking APX-LAMOTRIGINE, even if you feel

better, or change the dose without first checking with your doctor. Stopping this medicine suddenly may cause your epilepsy to come back or be worse. This is known as "rebound seizures".

Your doctor will advise you if you need to stop taking APX-LAMOTRIGINE and how to do it 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 APX-LAMOTRIGINE affects you.

Make sure you know how you react to it 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 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 APX-LAMOTRIGINE should be especially watchful for any changing behaviour.

Anti-epileptic medicines such as APX-LAMOTRIGINE may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

Side effects

Tell your doctor as soon as possible if you do not feel well

while you are taking APX-LAMOTRIGINE.

All medicines can have side effects. Sometimes 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 of APX-LAMOTRIGINE 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 APX-LAMOTRIGINE.

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 APX-LAMOTRIGINE.

All mentions of suicide or violence must be taken seriously. Families

and caregivers of children and adolescents who are taking this medicine should be especially watchful for any changing behaviour.

Anti-epileptic medicines such as APX-LAMOTRIGINE may increase the risk of suicidal behaviour (including suicidal thoughts and suicide attempts).

Potentially serious skin reaction

A small number of people taking APX-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 APX-LAMOTRIGINE especially if the dose is too high or if the dose is increased too quickly, or if it 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'
- 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

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 APX-LAMOTRIGINE if you experience these rare symptoms.

Potentially serious aseptic meningitis

APX-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 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.

After taking it

Storage

Keep your tablets in a cool dry place, protected from light and moisture, where the temperature stays below 25°C.

Keep APX-LAMOTRIGINE 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.

Do not store this 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.

Disposal

If your doctor tells you to stop taking APX-LAMOTRIGINE or your tablets have passed their expiry date, return any unused or expired medicine to your pharmacist.

Product description

What it looks like

APX-LAMOTRIGINE tablets come in 4 strengths: 25 mg, 50 mg, 100 mg & 200 mg.

The tablets are white to off-white, round, flat faced bevelled edge tablets, plain on both sides.

APX-LAMOTRIGINE 25mg

(AUST R 340907): White to off-white, modified square shape, engraved with "L" and "25" on one side, plain on the other side.

APX-LAMOTRIGINE 50mg

(AUST R 340908): White to off-white, modified square shape, engraved with "L" and "50" on one side, plain on the other side.

APX-LAMOTRIGINE 100mg

(AUST R 340909): White to off-white, modified square shape, engraved with "L" and "100" on one side, plain on the other side.

APX-LAMOTRIGINE 200mg

(AUST R 340910): White to off-white, modified square shape, engraved with "L" and "200" on one side, plain on the other side.

Available in blister packs of 56 tablets.

Ingredients

Active ingredient:

Each APX-LAMOTRIGINE tablet contains 25 mg, 50 mg, 100 mg or 200 mg of lamotrigine.

Inactive ingredients:

- calcium carbonate
- sorbitol
- microcrystalline cellulose
- crospovidone
- maize starch
- purified talc
- saccharin sodium
- sodium stearyl fumarate
- colloidal anhydrous silica
- blackcurrant flavour

APX-LAMOTRIGINE tablets are lactose, sucrose and gluten free.

This medicine contains saccharin.

Sponsor

Arrow Pharma Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

Australia

Australian registration numbers:

25 mg: AUST R 340907

50 mg: AUST R 340908

100 mg: AUST R 340909

200 mg: AUST R 340910

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