

APO-LAMOTRIGINE TABLET

Lamotrigine (25mg and 100mg)

What is in this leaflet

1. What Apo-Lamotrigine is used for
2. How Apo-Lamotrigine works
3. Before you use Apo-Lamotrigine
4. How to use Apo-Lamotrigine
5. While you are using it
6. Side effects
7. Storage and Disposal of Apo-Lamotrigine
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Apo-Lamotrigine is used for

Apo-Lamotrigine is used alone or in combination with other medicines to treat epilepsy or seizures.

How Apo-Lamotrigine works

This product contains active ingredient lamotrigine, which is an antiepileptic, that stabilizes electrical signals in the brain to stop seizures.

Before you use Apo-Lamotrigine

- When you must not take it

Do not use Apo-Lamotrigine if you are:

- allergic to lamotrigine or any other ingredients (listed in Product Description)

- Before you start to take it

To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child take Apo-Lamotrigine. Talk about any health conditions or problems you may have, including if you or your child:

- are taking any other antiepileptic drugs.
- are already taking lamotrigine or have previously taken lamotrigine, but had to stop taking it.
- have ever had a rash during previous treatment with lamotrigine or with any other antiepileptic drug.
- have ever had meningitis.
- are pregnant or are planning to become pregnant. Apo-Lamotrigine can cause birth defects if taken during pregnancy.

- are breast-feeding. Lamotrigine passes into breast milk and may cause side-effects in a breast-fed baby.
- are taking oral birth control pills or other female hormonal products.
- have liver, kidney or heart disease.
- have a family history of sudden cardiac death or suffer from a condition called Brugada syndrome (a genetic disease that affects the heart), or other heart problems (including problems with your heart rhythm).
- consume alcohol on a regular basis.
- have/had repeated infections.
- have had genetic testing and been told that you or your child are positive for the HLA-B*1502 allele, usually in people from Asian origin (mainly Han Chinese and Thai). The risk of serious skin reactions with lamotrigine may be associated with this genetic variant.

Other warnings you should know about:

Stopping your treatment: Do NOT suddenly stop taking Apo-Lamotrigine without talking to your healthcare professional first. If you do this, it may cause you to have more seizures. Stopping your treatment must be a gradual process that you discuss with your healthcare professional.

Suicidal thoughts and behaviour: If you have thoughts of harming or killing yourself at any time, contact a healthcare professional or go to a hospital right away. You may find it helpful to tell a relative or close friend how you are feeling and ask them to tell you if they notice any changes in your behaviour.

Pregnancy and lactation

Apo-Lamotrigine may harm your unborn baby. Only take Apo-Lamotrigine during pregnancy if you and your doctor have discussed the risks and have decided that you should. If you become pregnant while taking

Apo-Lamotrigine, talk to your healthcare professional.

Lamotrigine is secreted into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of breast feeding while you're taking lamotrigine.

- Taking other medicines

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

The following may interact with Apo-Lamotrigine:

- Other medications used to treat epilepsy such as, valproic acid (valproate), carbamazepine, phenytoin, phenobarbital, primidone.
- Risperidone, used to treat psychotic disorders (e.g., schizophrenia, bipolar disorder).
- Rifampin, an antibiotic used to treat bacterial infections.
- Procainamide, used to treat heart rhythm problems.
- Metformin, used to treat diabetes.
- Combination of lopinavir and ritonavir, or atazanavir and ritonavir, used in the treatment of HIV/AIDS.
- Birth control pills or other female hormonal products.
- Acetaminophen (rarely, cases of seizure have been reported).
- Any medications that affect your heart rhythm.
- Zonisamide, used to treat epilepsy and Parkinson's disease.

Do not start or stop using birth control pills or other female hormonal products, without consulting with your doctor.

Tell your doctor as soon as possible if you experience changes in your menstrual pattern (e.g., break-through bleeding) while taking Apo-Lamotrigine and birth control pills or other female hormonal products.

APO-LAMOTRIGINE TABLET

Lamotrigine (25mg and 100mg)

Apo-Lamotrigine may interfere with some laboratory tests to detect other drugs. If you require a laboratory test, tell the healthcare professional that you are taking Apo-Lamotrigine.

How to use Apo-Lamotrigine

Take Apo-Lamotrigine exactly as your healthcare professional has told you to.

Do not stop taking Apo-Lamotrigine suddenly as this can increase the number of seizures you have and their severity.

It is important to keep your appointments for medical checkups.

Apo-Lamotrigine can be taken with or without food.

Tablets: swallow tablets whole, do NOT chew or crush them.

- How much to use

Adults and children over 12 years old:

Your doctor will start with a low dose, and gradually increase the dose over a few weeks until a dose that works for you.

As single therapy:

The usual maintenance dose of lamotrigine is between 100mg and up to 500mg each day.

As combination with other antiepileptic medicine:

The usual maintenance dose of lamotrigine is between 100mg and up to 700mg each day.

Usual dose: Your healthcare professional will decide the best dose of Apo-Lamotrigine for you. They may increase or decrease the dose depending on your response to the medication. Carefully follow the instructions you were given. Do not change your dose unless your healthcare professional tells you to.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Apo-Lamotrigine for the duration that the doctor recommends. Treatment withdrawal or change of dosing should only follow recommendations of your doctor.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause abnormal eye movement, clumsiness and lack of co-ordination and balance, reduced consciousness or coma.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Apo-Lamotrigine.

Tell your doctor immediately if you become pregnant while using this medication.

Take Apo-Lamotrigine only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Apo-Lamotrigine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Patients with uncontrolled epilepsy should not drive or operate machinery. Apo-Lamotrigine may cause you to feel dizzy, drowsy, have poor coordination and/or blurred vision. Avoid doing tasks which require special attention until you know how Apo-Lamotrigine affects you.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These are not all the possible side effects you may have when taking Apo-Lamotrigine. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of Apo-Lamotrigine include:

- double vision, blurred vision
- headache
- tremor, poor coordination
- dizziness
- nausea, vomiting, upset stomach
- chest pain
- pain in your neck, abdomen, or joints
- feeling of weakness or tiredness (fatigue)
- sleepiness/drowsiness
- difficulty sleeping (insomnia)
- nasal congestion
- skin rash
- aggression, agitation or irritability
- anxiety
- nightmares.

Serious side effects:

Serious skin rashes:

While taking Apo-Lamotrigine, some people have developed serious skin reactions and have had to go to the hospital. There is a higher risk of developing a serious skin rash if

APO-LAMOTRIGINE TABLET

Lamotrigine (25mg and 100mg)

you:

- take more tablets than your doctor has told you to.
- are taking valproic acid.
- have a history of allergy or rash to other medications used to treat epilepsy.

Symptoms of a serious skin reaction may include:

- blistering or peeling of the skin that may start around the eyes, lips, mouth or genitals
- swelling of the face and/or tongue
- swollen lymph nodes
- hives
- fever

In children, a serious skin reaction can be mistaken for an infection. If you or your child develops a rash and fever while taking Apo-Lamotrigine, contact your doctor **immediately**.

Frequency (Very common):

- Skin rashes or redness

Frequency (Common):

- Worsening seizures: seizures happening more often in people who already have epilepsy

Frequency (Uncommon):

- Photosensitivity reaction: increased sensitivity of the skin to sunlight, exaggerated sun burn

Frequency (Rare):

- Aseptic meningitis (inflammation of the protective lining of the brain): fever, nausea, vomiting, sudden headache or stiff neck and extreme sensitivity to bright light
- Choreaathetosis (a movement disorder): abnormal uncontrollable muscle movements that may involve the face, eyes, nose, mouth/tongue, neck, trunk, arms or legs
- Conjunctivitis (eye infection): itchy, red eyes with discharge,

swelling and crusty eyelids

- Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blisters or crust in the center; possibly swollen lips, mild itching or burning
- Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body

Frequency (Very Rare):

- Blood problems: feeling very tired, fast heartbeat, shortness of breath, muscle weakness
- Haemophagocytic lymphohistiocytosis (HLH) (a serious overactive immune system condition that can lead to death): a high temperature (fever), skin rashes, trouble walking or seeing, and fits (seizures) for the first time or happening more often, enlarged liver and/or spleen with pain and/or tenderness in the region towards the top of the stomach, yellowing of the skin and/or eyes, swollen glands in the neck, armpit and/or groin, bleeding and/or bruising more easily; looking pale, feeling unusually tired
- Hallucinations (seeing or hearing things that aren't really there)
- Kidney problems: inflammation of the kidney felt as pain in the lower back and/or pain with urination (tubulointerstitial nephritis), which may occur with inflammation of the eye causing pain and/or visual disturbances (uveitis)
- Liver problems: yellowing of the skin and eyes, right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, unexplained loss of appetite
- Lymphadenopathy (swollen lymph nodes): swelling of the face or swollen glands in the neck, armpits or groin
- Pseudolymphoma (a non-cancerous skin condition that looks like lymphoma): red nodules or patches on the skin
- Serious blood clotting disorder (where you develop small blood clots throughout your body): unexpected or prolonged bleeding, including from your gums or nose, swelling with redness or pain in the area, bruising, blood in urine
- Drug reaction with eosinophilia and systemic symptoms (DRESS) (a serious skin reaction that can lead to death, it that may affect one or more organs): fever, severe rash, peeling skin, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine
- Multi-organ failure (failure of multiple organs such as the lungs, kidneys, heart, at the same time, this can lead to death): nausea or vomiting, less urine production, swelling of the ankles and feet, chest pain, difficulty breathing (at rest or with activity), seizures
- Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine
- Thoughts of suicide or hurting yourself

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

APO-LAMOTRIGINE TABLET

Lamotrigine (25mg and 100mg)

Storage and Disposal of Apo-Lamotrigine

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Product Description

- What it looks like

Apo-Lamotrigine 25mg: White tablet, shield-shaped, flat-faced, scored and engraved “25” on one side, and “APO” on the other side.

Apo-Lamotrigine 100mg: Peach tablet, shield-shaped, flat-faced, scored and engraved “LAM over 100” on one side, and “APO” on the other side.

- Ingredients

- Active ingredient(s)
Lamotrigine

- Inactive ingredients
25mg: Colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

100mg: Colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, sunset yellow aluminium lake

-MAL number:

25mg: MAL06091398ARZ

100mg: MAL06091396ARZ

Manufacturer

Apotex Inc.
150 Signet Drive Toronto, Ontario
Canada M9L 1T9

Product Registration Holder

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47810 Petaling Jaya, Malaysia

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