

LAMOTRIX TABLET

Lamotrigine (25mg, 50mg, 100mg, 200mg)

What is in this leaflet:

1. What LAMOTRIX is used for
2. How LAMOTRIX works
3. Before you use LAMOTRIX
4. How to use LAMOTRIX
5. While you are using it
6. Side effects
7. Storage and disposal of LAMOTRIX
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What LAMOTRIX is used for

LAMOTRIX is used as:

- an adjunctive therapy in treatment of partial seizures and generalised tonic-clonic seizures.
- a supplementary (add-on) treatment against seizure in connection with Lennox-Gastaut Syndrome in patients **more than 3** years of age.

How LAMOTRIX works

LAMOTRIX treats epilepsy by blocking the signals in the brain that trigger epileptic seizures.

LAMOTRIX is an antiepileptic medicine of the phenyltriazine class. Brain cells need to work at a certain rate to function normally. During a seizure, brain cells are forced to work much more rapidly than normal.

Before you use LAMOTRIX

When you must not use it

Do not take LAMOTRIX

- if you are allergic to lamotrigine or any of the other ingredients of this medicine (listed in Product description).
- If you have liver disease

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The medicine should not be used in pregnancy unless the benefit is considered to outweigh the potential risk for the foetus.

Lamotrigine is found in the milk in small amounts and may affect breast fed infants.

Breastfeeding is not recommended during lamotrigine therapy.

Before you start to use it

Talk to your healthcare providers before taking LAMOTRIX:

- If you ever had a rash during previous treatment with lamotrigine or with any other antiepileptic drug
- If you have liver or kidney disease.
- If you have a condition called *Brugada syndrome* (a genetic disease that affects the heart)

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken other medicines including medicines obtained without prescription.

If you are taking any of the medications below, please inform your doctor:

- anti-epileptic medicines such as valproate, carbamazepine, phenytoin, phenobarbital or primidone.
- any form of hormonal contraceptive (birth control pills)

How to use LAMOTRIX

How much to use

It is important to take LAMOTRIX exactly as instructed by your doctor. The dose of LAMOTRIX must be increased slowly. It may take several weeks or months before your final dosage can be determined by your doctor, based on your response.

Children aged 2 to 12 years: the effective dose depends on the body weight.

When to use it

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The tablets should be swallowed **whole** with a little water.

How long to use it

- Contact your doctor, if you stop taking LAMOTRIX for any reason. Do not restart without consulting your doctor.
- Continue taking LAMOTRIX for as long as your doctor recommends.

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)

- Never take more than the prescribed dose. If you suspect that you or someone else has taken an overdose of lamotrigine contact your doctor or go to the hospital at once. Always take the container with you, if possible, even if it is empty.
- The signs and symptoms of lamotrigine overdose may include: nystagmus (involuntary eye movements), lack of muscle coordination, dizziness, sleepiness, headache and vomiting.

While you are using it

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking LAMOTRIX.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not stop taking this medicine unless advised by your doctor
- Do not take any new medicines without consulting your doctor
- Do not give LAMOTRIX to anyone else, even if they have the same symptoms as you.
- Do not increase your dose of LAMOTRIX or take more frequent doses than those indicated by your doctor.

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Things to be careful of

Driving and using machines

In some individuals, Lamotrigine therapy may cause neurological type adverse reactions (such as dizziness, sleepiness). Therefore at the beginning of the treatment and until the response to Lamotrigine has been clarified, you are advised not to drive or operate machinery.

LAMOTRIX contains lactose monohydrate, which is a sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

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

Occurrence of side effects can vary depending on if LAMOTRIX is the only medicine used for treatment of epilepsy or if LAMOTRIX is part of a combined therapy with other anticonvulsants.

Tell your doctor if you experience any of the side effects after taking this medicine:

- headache
- tiredness
- rash
- nausea
- dizziness
- drowsiness
- insomnia

Side effects reported when lamotrigine is added on to standard antiepileptic drug regimens may include:

- diplopia (double vision), blurred vision, conjunctivitis
- dizziness, drowsiness, headache, unsteadiness, tiredness,
- gastrointestinal disturbance (including vomiting),
- irritability/aggression, tremor, agitation, confusion
- blood disorders (including neutropenia, leukopenia and thrombocytopenia).

If during treatment with LAMOTRIX you develop rash, fever or swelling of

face, it is important to contact your doctor immediately.

The highest risk for occurrence of serious skin reactions is within the first 2 months of treatment.

Lamotrigine may cause severe skin reactions, e.g. toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

There is a potential for an increase in risk of suicidal thoughts or behaviours in patients receiving anti-epileptic drugs, such as lamotrigine. Tell your doctor immediately if you have any thoughts of harming yourself or committing suicide.

Haemophagocytic lymphohistiocytosis (HLH)

There have been reports of a rare but very serious immune system reaction in patients taking lamotrigine.

Contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking lamotrigine: fever, rash, neurological symptoms (e.g. shaking or tremor, confusional state)

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)].

Storage and disposal of LAMOTRIX

Storage

- Keep this medicine out of the sight and reach of children.
- Store below 30°C in the original package.

Disposal

- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

- Do not throw away any medicines via wastewater or household waste.
- Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

What it looks like

- 25mg tablets are beige coloured, round, flat, marked MC at one side, with diameter 6mm.
- 50mg tablets are beige coloured, round, flat and have a break-line, with diameter 8mm.
- 100mg tablets are beige coloured, round, flat and have a break-line, with diameter 9.5mm.
- 200mg tablets are beige coloured, round, flat and have a break-line, with diameter 12.7mm.

Ingredients

Active ingredient

- The active substance is lamotrigine.

Inactive ingredients

- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate, iron oxide (yellow), ethanol 96%.

MAL No.

LAMOTRIX 25mg MAL20034651AZ
LAMOTRIX 50mg MAL20034652AZ
LAMOTRIX 100mg MAL20034653AZ
LAMOTRIX 200mg MAL20034654AZ

Manufacturer

MEDOCHEMIE (FAR EAST) LTD,
ORAL FACILITY No 40 street 6, VSIP II street 6, Vietnam-Singapore Industrial Park II, Binh Duong Industry service Urban complex, Hoa Phu Ward, Thu Dau Mot City, Binh Duong Province, Vietnam

Product Registration Holder

KOMEDIC SDN BHD, 4 Jalan PJS 11/14, Bandar Sunway 46150 Petaling Jaya, Selangor

Date of revision

21/07/2022

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