

PMS-LAMOTRIGINE TABLET

Lamotrigine (25mg, 100mg)

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What pms-Lamotrigine is used for

pms-Lamotrigine belongs to a group of medicines called anti-epileptics. It is indicated:

- as adjunctive (additional) therapy for the management of adults with epilepsy who are not satisfactorily controlled by conventional therapy
- as monotherapy (single) in adults following withdrawal of other concomitant antiepileptic medicines
- as adjunctive therapy for the management of seizures associated with Lennox-Gastaut syndrome (childhood-onset epilepsy) in children and adults.

How pms-Lamotrigine works

pms-Lamotrigine treats epilepsy by blocking the signals in the brain that trigger epileptic seizures (fits).

Before you use pms-Lamotrigine

- When you must not use it

Do not take pms-Lamotrigine tablets if you are allergic (hypersensitive) to lamotrigine or any of the other ingredients of pms-Lamotrigine tablets (*see ingredient list*).

Pregnancy and breastfeeding

Lamotrigine should only be used during pregnancy if the benefits of therapy outweigh the risks associated with it.

Lamotrigine passes into breast milk. Because of the potential for adverse reactions from lamotrigine in nursing infants, breastfeeding while taking this medication is not recommended. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Inform your doctor if you have any of the following conditions:

- kidney or liver impairment
- you have ever had a rash while taking lamotrigine or other medicines for epilepsy
- you are taking other medicines containing lamotrigine.

- Taking other medicines

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

Some medicines will affect the dose of pms-Lamotrigine you need. If you are taking any of the medications below, please inform your doctor:

- oxcarbazepine, lithium, olanzapine or bupropion
- other antiepileptic medicines such as phenytoin, carbamazepine, primidone, oxcarbamazepine and phenobarbitone.
- hormonal contraceptives
- rifampicin (antibiotic)

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use pms-Lamotrigine

- How much to use

Take the medicine exactly as advised by your doctor. Your doctor will start your treatment with a low dose and gradually increase it to achieve the suitable dose of pms-Lamotrigine for you.

For children aged 2 to 12 years, the effective dose depends on body weight.

Kidney or liver impairment

Your doctor will adjust the dose according to your condition.

Elderly above 65 years old

No dosage adjustment from recommended schedule is required.

- When to use it

Take pms-Lamotrigine tablets once or twice a day, as advised by your doctor. Always take the full dose prescribed by your doctor.

- How long to use it

Take pms-Lamotrigine tablets as long as your doctor prescribes it. Do not stop taking this medicine unless told to do so by your doctor.

- If you forget to use it

If you miss a dose, do not try to make up for it by doubling up on the next dose. Just take the next dose at the usual time. Consult your doctor or pharmacist if you have any doubts.

- If you use too much (overdose)

If you accidentally take an overdose of pms-Lamotrigine, contact your doctor or hospital immediately; if possible, show them the pack of tablets. Medical treatment may be required.

Symptoms of overdose:

- nystagmus (uncontrolled eye movements)

- ataxia (lack of muscle coordination)
- impaired consciousness
- coma

While you are using pms-Lamotrigine

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking pms-Lamotrigine.

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

Follow the instructions for the administration of pms-Lamotrigine exactly as your doctor tells you. Ask your doctor or pharmacist if you have any doubts.

- Things you must not do

Do not stop taking pms-Lamotrigine unless told to do so by your doctor.

Do not use pms-Lamotrigine to treat any other conditions unless your doctor tells you to.

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

- Things to be careful of

Driving and Handling Machines:

Lamotrigine can cause dizziness and blurred vision.

Do not drive or operate hazardous machinery until you know that you do not feel these symptoms. If you have epilepsy, talk to your doctor about driving or operating machinery.

Side effects

Like all medicines, pms-Lamotrigine can produce adverse effects, although not everyone suffers from them.

Common / very common side effects:

- headache
- skin rash
- irritability
- feeling sleepy
- feeling dizzy
- shaking or tremors
- difficulty in sleeping
- feeling agitated
- diarrhoea
- nausea or vomiting
- feeling tired
- pain in your back or joints, or elsewhere.

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of pms-Lamotrigine

- Storage

Store below 25°C in a dry cool place and protected from light. Keep out of reach of children.

- Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop

taking them, or you find that the expiry date has passed.

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 to protect the environment.

Product description

- What it looks like

25mg: White to off-white coloured, shield shaped tablets, engraved “P25” on one side and scored on the other side.

100mg: Peach-coloured, shield shaped tablets, engraved “P100” on one side and scored on the other side.

- Ingredients

Active Ingredient: Lamotrigine

Inactive Ingredients:
Cellulose, lactose, magnesium stearate, povidone, sodium starch glycolate, and the following coloring agent (in 100 mg tablet): FD&C Yellow No. 6 Lake 17.

- MAL number

25mg – MAL08111767ACRZ
100mg – MAL08111768ACRZ

Manufacturer

Wellspring Pharmaceutical Canada Corp.,
400 Iroquois Shore Road,
L6H1M5,
Oakville,
Canada.

Product Registration Holder

Medicell Pharmaceutical Malaysia Sdn Bhd (898390-M)
Suite 16-03, Menara AmFIRST,
1, Jalan 19/3, 46300 Petaling Jaya,
Selangor, Malaysia

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