

PART III: CONSUMER INFORMATION

Pr **pms-LAMOTRIGINE**
Lamotrigine Tablets, USP

This leaflet is part III of a "Product Monograph" published when pms-LAMOTRIGINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about pms-LAMOTRIGINE. Contact your doctor or pharmacist if you have any questions about the drug.

The information provided below is for patients, or parents of patients, who will be receiving pms-LAMOTRIGINE. Please read the following information carefully before you start to take pms-LAMOTRIGINE, even if you have taken this drug before. Please do not discard this leaflet; you may need to read it again.

ABOUT THIS MEDICATION

What the medication is used for:

pms-LAMOTRIGINE has been prescribed to you/your child to control your/their epilepsy. Please follow your doctor's recommendations carefully.

What it does:

pms-LAMOTRIGINE affects chemicals in the brain that are involved in sending signals to the nerves. pms-LAMOTRIGINE helps to control epileptic seizures.

When it should not be used:

Do NOT take or use pms-LAMOTRIGINE if you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of pms-LAMOTRIGINE tablets (see What the non-medicinal ingredients are).

What the medicinal ingredient is:

Lamotrigine

What the non-medicinal ingredients are:

Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, and the following:
100 mg tablets also include: FD&C Yellow no. 6
150 mg tablets also include: Yellow Iron Oxide.

What dosage forms it comes in:

Tablets: 25 mg, 100 mg and 150 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions – Serious Skin Rashes

Serious skin rashes requiring hospitalization have occurred with the use of lamotrigine. Symptoms include blistering,

peeling of the lips, eyes, mouth or genitals, swelling of the face and/or tongue, hives, swollen lymph nodes and fever. If you or your child develops these symptoms seek immediate medical help.

In children serious skin rashes can be mistaken for an infection. If your child develops a rash and fever while taking pms-LAMOTRIGINE contact your doctor immediately.

Do NOT take more tablets than has been prescribed by your doctor. There is a higher chance of serious skin reactions occurring when more than the recommended number of tablets is taken.

There is a higher chance of developing a serious skin rash if you have a history of allergy or rash to other anti-epileptic drugs. If you or your child has had a serious skin reaction or allergy to another anti-epileptic drug you must tell your doctor.

BEFORE you use pms-LAMOTRIGINE talk to your doctor or pharmacist if you or your child:

- Ever had an unusual or allergic reaction to pms-LAMOTRIGINE.
- Are/is allergic to any component of pms-LAMOTRIGINE tablets.
- Have ever had a rash during previous treatment with lamotrigine or with any other antiepileptic drug.
- Have ever developed meningitis after taking lamotrigine.
- Are/is pregnant or are planning to become pregnant. There is a risk of malformations (e.g., cleft lip or cleft palate) associated with the use of lamotrigine in the first few months of pregnancy. Taking folic acid when planning pregnancy and during early pregnancy may be considered. If you take pms-LAMOTRIGINE while pregnant, you may register yourself at the North American Antiepileptic Drug Pregnancy Registry (see contact number at the end of this information).
- Are/is breast-feeding (nursing). Lamotrigine passes into breast milk and may cause side-effects in a breast-fed baby. If the decision by you and your healthcare provider is to breast-feed while taking pms-LAMOTRIGINE, watch your baby closely for symptoms such as trouble breathing, episodes of temporarily stopping breathing, sleepiness or poor sucking. Call your baby's healthcare provider right away if you see any of these problems.
- Are/is taking any other prescription or over-the-counter medicine, including birth control pills or other female hormonal products.
- Have/has liver, kidney disease, heart problems or other medical conditions.
- Consume alcohol on a regular basis.

A small number of people taking lamotrigine get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems such as organ failure if not treated. You need to know the symptoms to look out for while

you are taking pms-LAMOTRIGINE. Please read the Serious Side Effects, How Often Do They Happen and What to do About Them section of this leaflet for more information.

There have been a small number of reports of suicidal behaviour (including suicidal thoughts and suicide attempts) in patients being treated with anti-epileptic medicines such as lamotrigine. If at any time you have these thoughts, contact your doctor immediately. **Do not discontinue pms-LAMOTRIGINE on your own.**

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking pms-LAMOTRIGINE. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a more severe seizure while you're taking pms-LAMOTRIGINE, contact a doctor as soon as possible.

Do not stop taking/giving pms-LAMOTRIGINE unless directed by your doctor. Always check that you have an adequate supply of pms-LAMOTRIGINE. Remember that this medicine was prescribed only for you/your child; never give it to anyone else.

Taking the wrong medication can cause serious health problems. When your healthcare provider gives you a prescription for pms-LAMOTRIGINE, make sure you can read it clearly and talk to your pharmacist to check that you are given the correct medicine.

Driving and using machines

Patients with uncontrolled epilepsy should not drive or operate machinery. Before doing tasks which require special attention, wait until you know how you respond to pms-LAMOTRIGINE. Dizziness, poor coordination, drowsiness, double vision and blurred vision have been reported in people taking lamotrigine.

INTERACTIONS WITH THIS MEDICATION

Consult your doctor before taking/giving your child any other medication, including over-the-counter medicines, herbal and alternative medicines. Some drugs can produce various side-effects when they are used in combination with pms-LAMOTRIGINE.

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 pms-LAMOTRIGINE and birth control pills or other female hormonal products.

pms-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 pms-LAMOTRIGINE.

Drug-Drug Interactions:

Drugs that may interact with pms-LAMOTRIGINE include:

- Valproic acid (valproate);
- Carbamazepine;

- Phenytoin;
- Phenobarbital;
- Primidone;
- Risperidone;
- Rifampin;
- Procainamide;
- Metformin;
- Combination of lopinavir and ritonavir, or atazanavir and ritonavir;
- Birth control pills or other female hormonal products.

PROPER USE OF THIS MEDICATION

Usual dose:

It is very important that you/your child take pms-LAMOTRIGINE exactly as your doctor instructed.

Your doctor may increase or decrease your/your child's medication according to your/their specific needs. Carefully follow the instructions you were given. Do not change the dose yourself.

If you plan to start or stop taking hormonal contraceptives or other female hormonal products, your doctor will give you specific instructions on the dose of pms-LAMOTRIGINE.

Do not stop taking your medication abruptly, because your/your child's seizures may increase. Speak to your doctor before stopping pms-LAMOTRIGINE.

It is important to keep your/your child's appointments for medical checkups.

pms-LAMOTRIGINE may be taken with or without food.

pms-LAMOTRIGINE tablets should be swallowed whole and should not be chewed or crushed.

Overdose:

If you think you/your child has taken too much pms-LAMOTRIGINE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child happen to miss a dose, take it as soon as you remember. If your next dose is less than 4 hours away, skip the missed dose and take the next dose at the normal time. Do not try to make up for it by doubling up on the next dose. Try not to miss any more doses. Ask your doctor for advice on how to start taking it again, even if you only stop for a few days.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects include:

- double vision, blurred vision;
- headache;
- tremor, poor coordination;
- dizziness;
- nausea, vomiting, stomach upset;
- 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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Skin rashes or redness		✓	
	Severe Skin Reactions: skin rashes or redness developing into widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals, sore mouth or eyes, a high temperature (fever), flu-like symptoms or drowsiness			✓
Rare	Choreoathetosis: abnormal uncontrollable muscle movements that may involve the face, eyes (nystagmus), neck, trunk, arms or legs	✓		
	Conjunctivitis: itchy eyes with discharge and crusty eyelids		✓	
	Aseptic meningitis: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light			✓
Very rare	Hallucinations: seeing or hearing things that aren't really there		✓	
	Nightmares	✓		
	Liver and blood problems: yellowing of the skin, itching,		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
abdominal pain and/or tenderness, feeling very tired, unexpected bleeding or bruising or the fingers turning blue, a sore throat or more infections (such as colds) than usual			
Lymphadenopathy: swelling of the face or swollen glands in the neck, armpits or groin		✓	
Serious blood clotting disorder: unexpected or prolonged bleeding, including from your gums or nose; blood in your urine; and unexpected bruising, including in the form of small dots on the skin.			✓
Not known	Thoughts of suicide or hurting yourself		✓
	Seizures happening more often in people who already have epilepsy		✓

This is not a complete list of side effects. For any unexpected effects while taking pms-LAMOTRIGINE contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C, in a dry place. Protect from light. Cap the bottle tightly immediately after use. **Keep out of sight and reach of children.**

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pharmascience Inc. at 1-888-550-6060.

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