

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

LAMOTRIGINE – 25
LAMOTRIGINE – 100
LAMOTRIGINE – 150
(Lamotrigine)

This leaflet is part III of a three-part “Product Monograph” published when 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 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 LAMOTRIGINE. Please read the following information carefully before you start to take 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:

LAMOTRIGINE, the brand name for lamotrigine, has been prescribed to you/your child to control your/their epilepsy. Please follow your doctor's recommendations carefully.

What it does:

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

When it should not be used:

Do NOT take or use LAMOTRIGINE if you are hypersensitive (allergic) to lamotrigine or any of the other ingredients of LAMOTRIGINE Tablets (see What the nonmedicinal ingredients are).

What the medicinal ingredient is:

The medicinal ingredient in LAMOTRIGINE is lamotrigine.

What the important nonmedicinal ingredients are:

The nonmedicinal ingredients in LAMOTRIGINE are: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, yellow aluminum lake (100 mg tablets only) and yellow ferric oxide (150 mg tablets only).

What dosage forms it comes in:

25 mg, 100 mg and 150 mg tablets.

WARNINGS AND PRECAUTIONS

Before you use LAMOTRIGINE talk to your doctor or pharmacist if you or your child:

- Ever had an unusual or allergic reaction to LAMOTRIGINE.
- Are/is allergic to any component of LAMOTRIGINE tablets.
- If you or your child 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. One reason for this is that a study has reported a risk of cleft lip or cleft palate associated with the use of LAMOTRIGINE in the first few months of pregnancy.
- Are/is breast-feeding (nursing).
- Are/is taking any other prescription or over-the counter medicine, including birth control pills or other female hormonal products.
- Have/has liver or 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. 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 LAMOTRIGINE on your own.**

The seizures in some types of epilepsy may occasionally become worse or happen more often while you're taking 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 LAMOTRIGINE, contact a doctor as soon as possible.

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

Patients prescribed LAMOTRIGINE have sometimes been given the wrong medicine because many medicines have similar names to LAMOTRIGINE, so always check that you receive LAMOTRIGINE.

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

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 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 LAMOTRIGINE and birth control pills or other female hormonal products.

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 LAMOTRIGINE.

Drug-Drug Interactions

Drugs that may interact with LAMOTRIGINE include:

- Valproic acid (valproate)
- Carbamazepine,
- Phenytoin,
- Phenobarbital
- Primidone
- Birth control pills or other female hormonal products.

Drug-Lifestyle Interactions

It is very important that you/your child do not perform any hazardous tasks such as driving or operating machinery.

PROPER USE OF THIS MEDICATION

Usual dose:

It is very important that you/your child take 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 LAMOTRIGINE.

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

LAMOTRIGINE may be taken with or without food.

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

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child happens to miss a dose, do not try to make up for it by doubling up on the dose next time. Just take/give the next regularly scheduled dose and try not to miss any more. 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

Like all medicines, LACMITAL can cause side effects, although not everybody gets them. The most common side effects include:

- double vision (diplopia), blurred vision
- tremor; poor coordination (ataxia)
- dizziness
- nausea; vomiting ; stomach upset
- pain in your neck, abdomen, or joints
- feeling of weakness or fatigue

IMPORTANT: PLEASE READ

- sleepiness/drowsiness (somnolence)
- difficulty sleeping (insomnia),
- nasal congestion (rhinitis)
- 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 right away		Stop taking drug and seek immediate emergency medical assistance
		Only if severe	In all cases	
Very common	Skin rashes or redness		√	
Rare	Skin rashes or redness, which may develop into severe skin reactions including 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	Abnormal uncontrollable muscle movements (choreoathetosis) that may involve the face, eyes (nystagmus), neck, trunk, arms or legs	√		

Rare	Conjunctivitis: symptoms like itchy eyes with discharge and crusty eyelids		√	
Rare	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		√	
Very Rare	Liver and blood problems [symptoms include yellowing of the skin, itching, 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]			√
Very Rare	swelling of the face or swollen glands in the neck, armpits or groin (symptoms for lymphadenopathy)			√

IMPORTANT: PLEASE READ

Very Rare	Serious blood clotting disorder with symptoms such as: 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		√	
Not known	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 LAMOTRIGINE contact your doctor or pharmacist.

HOW TO STORE IT

Store your LAMOTRIGINE tablets at room temperature (15°C to 30°C) in tight containers, in a dry place and protected from light. Cap the bottle tightly immediately after use..

Keep out of sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to : Canada Vigilance Program
Health Canada
Address Locator: 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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Last revised: December 1, 2015