

PART III: CONSUMER INFORMATION

**PrAPO-LAMOTRIGINE
(Lamotrigine Tablets)
Apotex Standard**

This leaflet is part III of a three-part “Product Monograph” published when APO-LAMOTRIGINE was for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-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 APO-LAMOTRIGINE. Please read the following information carefully before you start to take APO-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:

APO-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:

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

When it should not be used:

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

What the medicinal ingredient is:

lamotrigine.

What the important nonmedicinal ingredients are:

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

What dosage forms it comes in:

25 mg, 100 mg and 150 mg tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions – Serious Skin Rashes

Serious skin rashes requiring hospitalization have occurred with the use of APO-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 APO-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 APO-LAMOTRIGINE talk to your doctor or pharmacist if you or your child:

- Ever had an unusual or allergic reaction to APO-LAMOTRIGINE.
- Are/is allergic to any component of APO-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 APO-LAMOTRIGINE in the first few months of pregnancy. Taking folic acid when planning pregnancy and during early pregnancy may be considered. If you take APO-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). APO-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 APO-LAMOTRIGINE, watch your baby closely for symptoms such as trouble breathing, episodes of temporarily stopping breathing, sleepiness, rash, poor weight gain or poor sucking. Call your baby's healthcare provider right way 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.
- Have a family history of sudden cardiac death or suffer from a condition called Brugada syndrome (a genetic disease that affects the heart).
- Consume alcohol on a regular basis.
- Have/has repeated infections.

A small number of people taking **APO-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 **APO-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.

A very small number of patients taking **APO-LAMOTRIGINE** may experience a serious condition (haemophagocytic lymphohistiocytosis or HLH), in which part of the body that fights disease is overactive. If you have any of the side effects, contact your doctor immediately because, if not recognized early, this condition can be life-threatening. Please read the Serious Side Effects, How Often Do They Happen and What to do About Them table in this leaflet for more information and list of side effects.

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 **APO-LAMOTRIGINE**. If at any time you have these thoughts, contact your doctor immediately. **Do not discontinue APO-LAMOTRIGINE on your own.**

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

Do not stop taking/giving APO-LAMOTRIGINE unless directed by your doctor. Always check that you have an adequate supply of APO-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 APO-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 APO-LAMOTRIGINE. Dizziness, poor coordination, drowsiness, double vision and blurred vision have been reported in people taking APO-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 APO-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 APO-LAMOTRIGINE and birth control pills or other female hormonal products.

APO-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 APO-LAMOTRIGINE.

Drug-Drug Interactions

Drugs that may interact with APO-LAMOTRIGINE include:

- Valproic acid (valproate)
- Carbamazepine
- Phenytoin
- Phenobarbital

IMPORTANT: PLEASE READ

- 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 APO-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 APO-LAMOTRIGINE.

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

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

APO-LAMOTRIGINE may be taken with or without food.

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

Overdose:

If you think you have taken too much APO-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 happens 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 right away		seek immediate emergency medical help
		Only if severe	In all cases	
Very Common	Skin rashes or redness		✓	
Rare	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	✓		

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	(nystagmus), neck, trunk, arms or legs								
Rare	Conjunctivitis: 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		✓						
	Nightmares	✓							
Very Rare	Liver and blood Problems: 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	Lymphadenopathy: swelling of the face or swollen glands in the neck, armpits or groin (symptoms for lymphadenopathy)		✓						
Very Rare	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.								
Very Rare	Serious immune system condition: (haemophagocytic lymphohistiocytosis or HLH): 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								
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 APO-LAMOTRIGINE contact your doctor or pharmacist.

HOW TO STORE IT

Store your APO-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 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

If you want more information about APO-LAMOTRIGINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Consumer Information on the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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