

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### Pr **MYLAN-LAMOTRIGINE**

#### **Lamotrigine Tablets, USP**

Read this carefully before you start taking **MYLAN-LAMOTRIGINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYLAN-LAMOTRIGINE**.

#### **Serious Warnings and Precautions**

##### **Serious Skin Rashes:**

While taking MYLAN-LAMOTRIGINE, some people have developed serious skin reactions and have had to go to the hospital. There is a higher risk of developing a serious skin rash if you:

- take more tablets than your doctor has told you to.
- are taking valproic acid.
- have a history of allergy or rash to other medications used to treat epilepsy.

Symptoms of a serious skin reaction may include:

- blistering or peeling of the skin that may start around the eyes, lips, mouth or genitals
- swelling of the face and/or tongue
- swollen lymph nodes
- hives
- fever

In children, a serious skin reaction can be mistaken for an infection. If you or your child develops a rash and fever while taking MYLAN-LAMOTRIGINE, contact your doctor **immediately**.

#### **What is MYLAN-LAMOTRIGINE used for?**

MYLAN-LAMOTRIGINE is used in adults and children (who weigh at least 9 kg) to control epilepsy. Please follow your doctor's recommendations carefully.

#### **How does MYLAN-LAMOTRIGINE work?**

MYLAN-LAMOTRIGINE works by stopping your brain from releasing chemicals that are thought to be a cause of seizures. This helps to control epileptic seizures.

## **What are the ingredients in MYLAN-LAMOTRIGINE?**

Medicinal ingredients: lamotrigine

Non-medicinal ingredients: lactose anhydrous, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate.

In addition, the 100 mg (peach tablets) also contain Lake Blend Orange (FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake and FD&C Red #40/Allura Red AC Aluminium Lake) and the 150 mg (light yellow) also contain Iron Oxide Yellow.

## **MYLAN-LAMOTRIGINE comes in the following dosage forms:**

25 mg, 100 mg and 150 mg tablets

## **Do not use MYLAN-LAMOTRIGINE if:**

- you are allergic to lamotrigine or to any of the other ingredients of MYLAN-LAMOTRIGINE (see **What are the ingredients in MYLAN-LAMOTRIGINE?**).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child take MYLAN-LAMOTRIGINE. Talk about any health conditions or problems you may have, including if you or your child:**

- Are taking any other antiepileptic drugs.
- Are already taking lamotrigine or have previously taken lamotrigine, but had to stop taking it.
- Have ever had a rash during previous treatment with lamotrigine or with any other antiepileptic drug.
- Have ever had meningitis.
- Are pregnant or are planning to become pregnant. MYLAN-LAMOTRIGINE can cause birth defects if taken during pregnancy.
- Are breast-feeding. MYLAN-LAMOTRIGINE passes into breast milk and may cause side-effects in a breast-fed baby.
- Are taking oral birth control pills or other female hormonal products.
- Have liver, kidney or heart disease.
- Have a family history of sudden cardiac death or suffer from a condition called Brugada syndrome (a genetic disease that affects the heart), or other heart problems (including problems with your heart rhythm).
- Consume alcohol on a regular basis.
- Have/has repeated infections.

## **Other warnings you should know about:**

**Stopping your treatment:** Do NOT suddenly stop taking MYLAN-LAMOTRIGINE without talking to your healthcare professional first. If you do this, it may cause you to have more seizures. Stopping your treatment must be a gradual process that you discuss with your healthcare professional.

**Pregnancy:** MYLAN-LAMOTRIGINE may harm your unborn baby. Only take MYLAN-LAMOTRIGINE during pregnancy if you and your doctor have discussed the risks and have decided that you should. If you become pregnant while taking MYLAN-LAMOTRIGINE, talk to your healthcare professional about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy. Information on the registry can also be found at the following website: <http://www.aedpregnancyregistry.org/>.

**Suicidal thoughts and behaviour:** If you have thoughts of harming or killing yourself at any time, contact a healthcare professional or go to a hospital **right away**. You may find it helpful to tell a relative or close friend how you are feeling and ask them to tell you if they notice any changes in your behaviour.

**Driving and using machines:** Patients with uncontrolled epilepsy should not drive or operate machinery. MYLAN-LAMOTRIGINE may cause you to feel dizzy, drowsy, have poor coordination and/or blurred vision. Avoid doing tasks which require special attention until you know how MYLAN-LAMOTRIGINE affects you.

**Tell your healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with MYLAN-LAMOTRIGINE:**

- Other medications used to treat epilepsy such as, valproic acid (valproate), carbamazepine, phenytoin, phenobarbital, primidone
- Risperidone, used to treat psychotic disorders (e.g., schizophrenia, bipolar disorder)
- Rifampin, an antibiotic used to treat bacterial infections
- Procainamide, used to treat heart rhythm problems
- Metformin, used to treat diabetes
- Combination of lopinavir and ritonavir, or atazanavir and ritonavir, used in the treatment of HIV/AIDS
- Birth control pills or other female hormonal products.
- Acetaminophen (rarely, cases of seizure have been reported)
- Any medications that affect your heart rhythm
- Zonisamide (**not available in Canada**), used to treat epilepsy and Parkinson's disease

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

MYLAN-LAMOTRIGINE may interfere with some laboratory tests to detect other drugs. If you require a laboratory test, tell the healthcare professional that you are taking MYLAN-LAMOTRIGINE.

### **How to take MYLAN-LAMOTRIGINE:**

- Take MYLAN-LAMOTRIGINE exactly as your healthcare professional has told you to.
- Do not stop taking MYLAN-LAMOTRIGINE suddenly as this can increase the number of seizures you have and their severity.
- It is important to keep your appointments for medical checkups.
- MYLAN-LAMOTRIGINE can be taken with or without food.
- Swallow tablets whole, do NOT chew or crush them.

### **Usual dose:**

Your healthcare professional will decide the best dose of MYLAN-LAMOTRIGINE for you. They may increase or decrease the dose depending on your response to the medication. Carefully follow the instructions you were given. Do not change your dose unless your healthcare professional tells you to.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much MYLAN-LAMOTRIGINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### **Missed Dose:**

If you miss a dose, take it as soon as you remember. However, 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 healthcare professional for advice on how to start taking it again, even if you only stop for a few days.

### **What are possible side effects from using MYLAN-LAMOTRIGINE?**

These are not all the possible side effects you may have when taking MYLAN-LAMOTRIGINE. If you experience any side effects not listed here, tell your healthcare professional.

- double vision, blurred vision
- headache
- tremor, poor coordination
- dizziness
- nausea, vomiting, upset stomach
- chest pain
- 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
- anxiety

- nightmares

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Skin rashes or redness		✓	
COMMON			
Worsening seizures: seizures happening more often in people who already have epilepsy			✓
RARE			
Aseptic meningitis (inflammation of the protective lining of the brain): fever, nausea, vomiting, sudden headache or stiff neck and extreme sensitivity to bright light			✓
Choreoathetosis (a movement disorder): abnormal uncontrollable muscle movements that may involve the face, eyes, nose, mouth/tongue, neck, trunk, arms or legs	✓		
Conjunctivitis (eye infection): itchy, red eyes with discharge, swelling and crusty eyelids		✓	
Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body			✓
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blisters or crust in the center; possibly swollen lips, mild itching or burning			✓
VERY RARE			
Blood problems: feeling very tired, fast heartbeat, shortness of breath, muscle weakness		✓	
Haemophagocytic lymphohistiocytosis (HLH) (a serious overactive immune system			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
condition that can lead to death): 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			
<b>Hallucinations</b> (seeing or hearing things that aren't really there)		✓	
<b>Kidney problems:</b> inflammation of the kidney felt as pain in the lower back and/or pain with urination (tubulointerstitial nephritis), which may occur with inflammation of the eye causing pain and/or visual disturbances (uveitis)		✓	
<b>Liver problems:</b> yellowing of the skin and eyes, right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, unexplained loss of appetite		✓	
<b>Lymphadenopathy</b> (swollen lymph nodes): swelling of the face or swollen glands in the neck, armpits or groin		✓	
<b>Serious blood clotting disorder</b> (where you develop small blood clots throughout your body): unexpected or prolonged bleeding, including from your gums or nose, swelling with redness or pain in the area, bruising, blood in urine			✓
<b>UNKNOWN FREQUENCY</b>			
<b>Drug reaction with eosinophilia and systemic symptoms (DRESS)</b>			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
(a serious skin reaction that can lead to death, it that may affect one or more organs): fever, severe rash, peeling skin, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine			
<b>Multi-organ failure</b> (failure of multiple organs such as the lungs, kidneys, heart, at the same time, this can lead to death): nausea or vomiting, less urine production, swelling of the ankles and feet, chest pain, difficulty breathing (at rest or with activity), seizures			✓
<b>Rhabdomyolysis</b> (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine			✓
Thoughts of suicide or hurting yourself		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### 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.*

### Storage:

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

Keep out of reach and sight of children.

### If you want more information about MYLAN-LAMOTRIGINE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.mylan.ca](http://www.mylan.ca), or by calling 1-800-596-9526.

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