

Patient Education LAMOTRIGINE - ORAL

IMPORTANT: HOW TO USE THIS INFORMATION: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

LAMOTRIGINE – ORAL COMMON BRAND NAME(S): Lamictal

WARNING: Rarely, serious (sometimes fatal) skin rashes have occurred while taking this medication. These rashes are more common in children under 16 than in adults. Rashes may be more likely if you start at too high a dose, if you increase your dose too quickly, or if you take this medication with certain other anti-seizure medications (valproic acid, divalproex). These rashes may occur anytime during use, but most serious rashes have occurred within 2 to 8 weeks of starting lamotrigine.

Get medical help right away if you develop any type of skin rash while taking this medication, or if you have other signs of a serious allergic reaction such as hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, or swelling of the lips or tongue. Your doctor will tell you if you should stop taking lamotrigine. Even after you stop taking this medication, it is still possible for the rash to become life-threatening or cause permanent scars or other problems.

USES:

Lamotrigine is used alone or with other medications to prevent and control seizures. It may also be used to help prevent the extreme mood swings of bipolar disorder in adults.

Lamotrigine is known as an anticonvulsant or antiepileptic drug. It is thought to work by restoring the balance of certain natural substances in the brain.

HOW TO USE:

Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start taking lamotrigine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth with or without food as directed by your doctor. Swallow the tablets whole since chewing them may leave a bitter taste.

Dosage is based on your medical condition, response to treatment, and use of certain interacting drugs. (See also Drug Interactions section.) For children, the dosage is also based on weight.

It is very important to follow your doctor's dosing instructions exactly. The dose must be increased slowly. It may take several weeks or months to reach the best dose for you and to get the full benefit from this medication. Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time(s) each day.

Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is suddenly stopped. Your dose may need to be gradually decreased. Also, if you have stopped taking this medication, do not restart lamotrigine without consulting your doctor.

Tell your doctor if your condition does not improve or if it worsens.

SIDE EFFECTS:

See also Warning section.

Dizziness, drowsiness, headache, blurred/double vision, loss of coordination, shaking (tremor), nausea, vomiting, or upset stomach may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

A small number of people who take anticonvulsants for any condition (such as seizures, bipolar disorder, pain) may experience depression, suicidal thoughts/attempts, or other mental/mood problems. Tell your doctor right away if you or your family/caregiver notice any unusual/sudden changes in your mood, thoughts, or behavior including signs of depression, suicidal thoughts/attempts, thoughts about harming yourself.

Tell your doctor right away if any of these rare but serious side effects occur: easy or unusual bruising/bleeding, unusual tiredness, signs of infection (such as fever, stiff neck, persistent sore throat), muscle pain/tenderness/weakness, dark urine, yellowing eyes/skin, stomach/abdominal pain, persistent nausea/vomiting, change in the amount of urine.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking lamotrigine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease.

This drug may make you dizzy or drowsy or cause blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. However, since untreated seizures are a serious condition that can harm both a pregnant woman and her unborn baby, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately talk to your doctor about the benefits and risks of using this medication during pregnancy. Since birth control pills, patches, implants, and injections may not work if taken with this medication (see also Drug Interactions section), discuss reliable forms of birth control with your doctor.

This drug passes into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Other medications can affect the removal of lamotrigine from your body, which may affect how lamotrigine works. Examples include hormonal birth control (such as pills, patches), estrogens, other medications to treat seizures (such as carbamazepine, phenobarbital, phenytoin, primidone, valproic acid), and rifampin, among others. Your doctor may need to adjust your dose of lamotrigine if you are on these medications.

This medication may decrease the effectiveness of hormonal birth control products (such as pills, patch, ring). This effect can result in pregnancy. Ask your doctor or pharmacist for details. Discuss whether you should use additional reliable birth control methods while using this medication. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and narcotic pain relievers (such as codeine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

OVERDOSE:

If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: severe drowsiness, unusual eye movements, loss of consciousness.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (such as liver and kidney function tests, complete blood count) may be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

There are different types of this medication available. Some do not have the same effects. There are also some medications that sound the same as this product. Make sure you have the right product before taking it.

MISSED DOSE:

It is important to take each dose at the scheduled time. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (US) or 1-800-668-1507 (Canada).