

**NDA 022509 - FDA Approved Labeling Text dated 1/29/10**  
**Lamictal XR (lamotrigine) Extended-Release Tablets**

reactions or changes in menstrual pattern (e.g., break-through bleeding) while receiving LAMICTAL XR in combination with these medications.

**17.8 Discontinuing LAMICTAL XR**

Patients should be advised to notify their physician if they stop taking LAMICTAL XR for any reason and not to resume LAMICTAL XR without consulting their physician.

**17.9 Potential Medication Errors**

Medication errors involving LAMICTAL have occurred. In particular the names LAMICTAL or lamotrigine can be confused with the names of other commonly used medications. Medication errors may also occur between the different formulations of LAMICTAL. To reduce the potential of medication errors, write and say LAMICTAL XR clearly. Depictions of the LAMICTAL XR Extended-Release Tablets can be found in the Medication Guide in section 17.10. Each LAMICTAL XR tablet has a distinct color and white center, and is printed with “LAMICTAL XR” and the tablet strength. These distinctive features serve to identify the different presentations of the drug and thus may help reduce the risk of medication errors. LAMICTAL XR is supplied in round, unit-of-use bottles with orange caps containing 30 tablets. The label on the bottle includes a depiction of the tablets which further communicates to patients and pharmacists that the medication is LAMICTAL XR and the specific tablet strength included in the bottle. The unit-of-use bottle with a distinctive orange cap and distinctive bottle label features serves to identify the different presentations of the drug and thus may help to reduce the risk of medication errors. **To avoid a medication error of using the wrong drug or formulation, patients should be strongly advised to visually inspect their tablets to verify that they are LAMICTAL XR each time they fill their prescription and to immediately talk to their doctor/pharmacist if they receive a LAMICTAL XR tablet without a white center and without “LAMICTAL XR” and the strength printed on the tablet as they may have received the wrong medication** [see *Dosage Forms and Strengths (3), How Supplied/Storage and Handling (16)*].

**17.10 Medication Guide**

A Medication Guide is provided as a separate leaflet accompanying the product. The full text of the Medication Guide is reprinted below.

**MEDICATION GUIDE**

**LAMICTAL<sup>®</sup> (la-MIK-tal) XR<sup>™</sup> (lamotrigine) Extended-Release  
Tablets**

Read this Medication Guide before you start taking LAMICTAL XR and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. If you have questions about LAMICTAL XR, ask your healthcare provider or pharmacist.

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**What is the most important information I should know about LAMICTAL XR?**

**1. LAMICTAL XR may cause a serious skin rash that may cause you to be hospitalized or to stop LAMICTAL XR; it may rarely cause death.**

There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when you begin taking LAMICTAL XR, within the first 2 to 8 weeks of treatment. But it can happen in people who have taken LAMICTAL XR for any period of time. Children between 2 to 16 years of age have a higher chance of getting this serious skin reaction while taking lamotrigine. LAMICTAL XR is not approved for use in children less than 13 years old.

The risk of getting a rash is higher if you:

- take LAMICTAL XR while taking valproate (DEPAKENE (valproic acid) or DEPAKOTE (divalproex sodium)).
- take a higher starting dose of LAMICTAL XR than your healthcare provider prescribed.
- increase your dose of LAMICTAL XR faster than prescribed.

**LAMICTAL XR can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions.**

**Call your healthcare provider right away if you have any of the following:**

- a skin rash
- hives
- fever
- swollen lymph glands
- painful sores in the mouth or around your eyes
- swelling of your lips or tongue
- yellowing of your skin or eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections

These symptoms may be the first signs of a serious reaction. A healthcare provider should examine you to decide if you should continue taking LAMICTAL XR.

**2. Like other antiepileptic drugs, LAMICTAL XR may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

**Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**

- thoughts about suicide or dying

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- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

**Do not stop LAMICTAL XR without first talking to a healthcare provider.**

- Stopping LAMICTAL XR suddenly can cause serious problems.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

**How can I watch for early symptoms of suicidal thoughts and actions?**

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

**LAMICTAL XR can have other serious side effects.** For more information ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you. Be sure to read the section below entitled “What are the possible side effects of LAMICTAL XR?”

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

Taking the wrong medication can cause serious health problems. When your healthcare provider gives you a prescription for LAMICTAL XR:

- Make sure you can read it clearly.
- Talk to your pharmacist to check that you are given the correct medicine.
- Each time you fill your prescription, check the tablets you receive against the pictures of the tablets below.

These pictures show the distinct wording, colors, and shapes of the tablets that help to identify the right strength of LAMICTAL XR. Immediately call your pharmacist if you receive a LAMICTAL XR tablet that does not look like one of the tablets shown below, as you may have received the wrong medication.

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**LAMICTAL XR (lamotrigine) Extended-Release Tablets**

 <b>25 mg, yellow with white center Imprinted with LAMICTAL XR 25</b>	 <b>50 mg, green with white center Imprinted with LAMICTAL XR 50</b>	 <b>100 mg, orange with white center Imprinted with LAMICTAL XR 100</b>	 <b>200 mg, blue with white center Imprinted with LAMICTAL XR 200</b>
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**What is LAMICTAL XR?**

LAMICTAL XR is a prescription medicine used together with other medicines to treat primary generalized tonic-clonic seizures and partial onset seizures in people 13 years or older. It is not known if LAMICTAL XR is safe or effective in children under the age of 13. Other forms of LAMICTAL can be used in children 2 to 12 years.

**Who should not take LAMICTAL XR?**

You should not take LAMICTAL XR if you have had an allergic reaction to lamotrigine or to any of the inactive ingredients in LAMICTAL XR. See the end of this leaflet for a complete list of ingredients in LAMICTAL XR.

**What should I tell my healthcare provider before taking LAMICTAL XR?**

Before taking LAMICTAL XR, tell your healthcare provider about all of your medical conditions, including if you:

- have had a rash or allergic reaction to another antiseizure medicine.
- have or have had depression, mood problems or suicidal thoughts or behavior.
- are taking oral contraceptives (birth control pills) or other female hormonal medicines. Do not start or stop taking birth control pills or other female hormonal medicine until you have talked with your healthcare provider. Tell your healthcare provider if you have any changes in your menstrual pattern such as breakthrough bleeding. Stopping these medicines may cause side effects (such as dizziness, lack of coordination, or double vision). Starting these medicines may lessen how well LAMICTAL XR works.
- are pregnant or plan to become pregnant. It is not known if LAMICTAL XR will harm your unborn baby. If you become pregnant while taking LAMICTAL XR, talk to your healthcare provider 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 drugs during pregnancy.
- are breastfeeding. LAMICTAL XR can pass into your breast milk. You and your healthcare provider should decide if you should take LAMICTAL XR or breastfeed. Breastfeeding

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while taking LAMICTAL XR is not recommended.

Tell your healthcare provider about all the medicines you take or if you are planning to take a new medicine, including prescription and non-prescription medicines, vitamins, and herbal supplements. Using LAMICTAL XR with certain other medicines can affect each other, causing side effects.

**How should I take LAMICTAL XR?**

- Take LAMICTAL XR exactly as prescribed.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Do not stop taking LAMICTAL XR without talking to your healthcare provider. Stopping LAMICTAL XR suddenly may cause serious problems. For example, if you have epilepsy and you stop taking LAMICTAL XR suddenly, you may get seizures that do not stop. Talk with your healthcare provider about how to stop LAMICTAL XR slowly.
- If you miss a dose of LAMICTAL XR, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not take two doses at the same time.**
- You may not feel the full effect of LAMICTAL XR for several weeks.
- If you have epilepsy, tell your healthcare provider if your seizures get worse or if you have any new types of seizures.
- LAMICTAL XR can be taken with or without food.
- Do not chew, crush, or divide LAMICTAL XR.
- Swallow LAMICTAL XR tablets whole.
- If you have trouble swallowing LAMICTAL XR Tablets, tell your healthcare provider because there may be another form of LAMICTAL you can take.
- If you receive LAMICTAL XR in a blisterpack, examine the blisterpack before use. Do not use if blisters are torn, broken, or missing.

**What should I avoid while taking LAMICTAL XR?**

- Do not drive a car or operate complex, hazardous machinery until you know how LAMICTAL XR affects you.

**What are possible side effects of LAMICTAL XR?**

- See “What is the most important information I should know about LAMICTAL XR?”

Common side effects of LAMICTAL XR include:

- Dizziness
- Tremor
- Double vision

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- Nausea
- Vomiting
- Trouble with balance and coordination
- Anxiety

Other common side effects that have been reported with another form of LAMICTAL include headache, sleepiness, blurred vision, runny nose, and rash.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of LAMICTAL XR. For more information, ask your healthcare provider or pharmacist.

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

**How should I store LAMICTAL XR?**

- Store LAMICTAL XR at room temperature between 59°F to 86°F (15°C to 30°C).
- **Keep LAMICTAL XR and all medicines out of the reach of children.**

**General information about LAMICTAL XR**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LAMICTAL XR for a condition for which it was not prescribed. Do not give LAMICTAL XR to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about LAMICTAL XR. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about LAMICTAL XR that is written for healthcare professionals.

For more information, go to [www.lamictalxr.com](http://www.lamictalxr.com) or call 1-888-825-5249.

**What are the ingredients in LAMICTAL XR?**

Active ingredient: Lamotrigine.

Inactive ingredients: glycerol monostearate, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer dispersion, polyethylene glycol 400, polysorbate 80, silicon dioxide (25-mg and 50-mg tablets only), titanium dioxide, triethyl citrate, iron oxide black (50-mg tablet only), iron oxide yellow (25-mg, 50-mg, 100-mg tablets only), iron oxide red (100-mg tablet only), FD&C Blue No. 2 Aluminum Lake (200-mg tablet only). Tablets are printed with edible black ink.

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**This Medication Guide has been approved by the U.S. Food and Drug Administration.**

(Date of Issue)

LXR:



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