Lamotrigine (la-moe-trig-ine) Tablets, USP

What is the most important information I should know about lamotrigine?

1. Lamotrigine may cause a severe skin rash that may cause you to be hospitalized or even cause death. There is no way to tell if a mild rash will become more serious. A serious skin rash can happen at any time during your treatment with lamotrigine, but is more likely to happen within the first 2 to 8 weeks of treatment. Children and teenagers aged between 2 and 17 years have a higher chance of getting this serious skin rash while taking lamotrigine.

2. Call your healthcare provider right away if you have any of the following:
   - a skin rash
   - blisters or peeling of your skin
   - hives
   - painful sores in your mouth or around your eyes
   - fever
   - frequent infections
   - severe muscle pain
   - swelling of your face, eyes, lips, or tongue
   - swollen lymph glands
   - uncontrolled bleeding
   - weakness, fatigue
   - yellowing of your skin or the white part of your eyes

3. Other serious reactions, including serious but non-life-threatening problems or life-threatening problems.

   Lamotrigine can cause other types of skin reactions or serious problems that may affect organs and other parts of your body like your liver or thyroid 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 these symptoms:
   - blisters or peeling of your skin
   - hives
   - painful sores in your mouth or around your eyes
   - fever
   - frequent infections
   - severe muscle pain
   - swelling of your face, eyes, lips, or tongue
   - swollen lymph glands
   - uncontrolled bleeding
   - weakness, fatigue
   - yellowing of your skin or the white part of your eyes

4. Lamotrigine may cause aseptic meningitis, an inflammation of the protective membrane that covers the brain and spinal cord.

   Call your healthcare provider right away if you have any of the following symptoms:
   - headache
   - fever
   - nausea
   - vomiting
   - stiff neck
   - rash
   - unusual sensitivity to light
   - muscle pains
   - cough
   - confusion
   - croupiness

   Meningitis has many causes other than lamotrigine, which your doctor would check for if you developed meningitis while taking lamotrigine.

5. Lamotrigine can cause severe 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 lamotrigine?”

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

   Taking the wrong medicine can cause serious health problems. When your healthcare provider gives you a prescription for lamotrigine:
   - Make sure you can read it clearly.
   - Talk to your pharmacist to check that you receive 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, coloring, and shapes of the tablets that help to identify the right strength of lamotrigine tablets, USP. Immediately call your pharmacist if you receive a lamotrigine tablet, USP that does not look like one of the tablets shown below, as you may have received the wrong medication.

Lamotrigine Tablets, USP

<table>
<thead>
<tr>
<th>Tablet Strength</th>
<th>Lamotrigine Tablets (equal to)</th>
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<tbody>
<tr>
<td>50 mg</td>
<td>100 mg</td>
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What is lamotrigine?

Lamotrigine is a prescription medicine used:
- together with other medicines to treat certain types of seizures (partial-onset seizures, primary generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome) in people aged 2 years and older
- alone when changing from 1 other medicine used to treat partial-onset seizures in people aged 16 years and older
- for the long-term treatment of bipolar I disorder to lengthen the time between mood episodes in people who have been treated for mood episodes with other medicine

Lamotrigine is not known if lamotrigine is safe or effective in people younger than 18 years with mood episodes such as bipolar disorder or depression.

Lamotrigine is not known if lamotrigine is safe or effective when used alone as the first treatment of seizures.

Lamotrigine is not safe or effective for people with mood episodes who have not already been treated with other medicine.

Lamotrigine should not be used for acute treatment of manic or mixed mood episodes.

Do not take lamotrigine:
- if you are allergic to lamotrigine or to any of the inactive ingredients in lamotrigine. See the end of this leaflet for a complete list of ingredients in lamotrigine.

Before taking lamotrigine, tell your healthcare provider about all of your health conditions, including if you:
- have had a rash or allergic reaction to another antiepileptic medicine, or
- have had depression, mood swings, or suicidal thoughts or behaviors, or
- have had aseptic meningitis after taking lamotrigine.

- 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 while you are taking lamotrigine may cause side effects (such as dizziness, lack of coordination, or double vision). Stopping these medicines may lessen how well lamotrigine works.

- are pregnant or plan to become pregnant. It is not known if lamotrigine will harm your unborn baby. If you become pregnant while taking lamotrigine, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-331-0411 or visit www.aedpregnancy.org. This registry is to collect information about the safety of antiepileptic drugs during pregnancy.

- are breastfeeding. Lamotrigine passes into breast milk. There is a possibility of temporarily stopping breathing, sleepiness, or poor sucking. Call your baby’s healthcare provider right away if you see any of these problems. Talk to your healthcare provider about how to help your baby feed if you take lamotrigine.

Tell your healthcare provider about all of the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. Lamotrigine and certain other medicines may interact with each other. This may cause serious side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take lamotrigine?

Take lamotrigine 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 lamotrigine without talking to your healthcare provider. Stopping lamotrigine suddenly may cause serious problems.

For more information, call 1-800-222-1222.

What are the ingredients in lamotrigine tablets, USP?

Active ingredient: lamotrigine. USP.

Inactive ingredients: lactose monohydrate; magnesium stearate; microcrystalline cellulose; povidone; and sodium starch glycolate.