

MEDICATION GUIDE

Lamotrigine Tablets USP

Read this Medication Guide before you start taking lamotrigine 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 lamotrigine, ask your healthcare provider or pharmacist.

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

1. Lamotrigine may cause a serious 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 between 2 to 16 years of age have a higher chance of getting this serious skin rash while taking lamotrigine.

The risk of getting a serious skin rash is higher if you:

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

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

- **a skin rash**
- **blistering or peeling of your skin**
- **hives**
- **painful sores in your mouth or around your eyes**

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

2. Other serious reactions, including serious blood problems or liver problems.

Lamotrigine can also cause other types of allergic reactions or serious problems that may affect organs and other parts of your body like your 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 these symptoms:

- fever
- frequent infections
- severe muscle pain
- swelling of your face, eyes, lips, or tongue
- swollen lymph glands
- unusual bruising or bleeding
- weakness, fatigue
- yellowing of your skin or the white part of your eyes

3. **Like other antiepileptic drugs, lamotrigine 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
- 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 lamotrigine without first talking to a healthcare provider.

- Stopping lamotrigine 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.

4. **Lamotrigine may rarely cause aseptic meningitis, a serious 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
- Chills
- Confusion
- Drowsiness

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

Lamotrigine 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 lamotrigine?**”

5. Patients 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 medication 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 are given the correct medicine.
- Each time you fill your prescription, check the tablets you receive against the description of the tablets below.

The below wording describes the color and embossing that is on each strength of lamotrigine tablet. Before taking your medicine, it is important to compare the tablets you receive from your doctor or pharmacist with these wordings to make sure you have received the correct medicine.

Lamotrigine Tablets USP

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| 25 mg are light yellow, round, flat, bevel edged, uncoated tablets, embossed “RDY” on one side and “220” on other side with bisect line. | 100 mg are light yellow, round, flat, bevel edged, uncoated tablets, embossed “RDY” on one side and “221” on other side with bisect line. | 150 mg are light yellow, round, flat, bevel edged, uncoated tablets, embossed “RDY” on one side and “222” on other side with bisect line. | 200 mg are light yellow, round, flat, bevel edged, uncoated tablets, embossed “RDY” on one side and “223” on other side with bisect line. |
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What is lamotrigine?

Lamotrigine is a prescription medicine used:

1. together with other medicines to treat certain types of seizures (partial seizures, primary generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome) in people 2 years or older.
2. alone when changing from other medicines used to treat partial seizures in people 16 years or older.
3. for the long-term treatment of Bipolar I Disorder to lengthen the time between mood episodes in people 18 years or older who have been treated for mood episodes with other medicine.

It is not known if lamotrigine is safe or effective in children or teenagers under the age of 18 with mood disorders such as bipolar disorder or depression.

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

Who should not take lamotrigine?

You should not take lamotrigine if you have had an allergic reaction 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.

What should I tell my healthcare provider before taking lamotrigine?

Before taking lamotrigine, 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 medicine may cause side effects (such as dizziness, lack of coordination, or double vision). Starting these medicine 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 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- are breastfeeding. Lamotrigine can pass into your breast milk. You and your healthcare provider should decide if you should take lamotrigine or breastfeed. Breastfeeding while taking lamotrigine 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. If you use lamotrigine with certain other medicines can affect each other, causing side effects.

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 example, if you have epilepsy and you stop taking lamotrigine suddenly, you may get seizures that do not stop. Talk with your healthcare provider about how to stop lamotrigine slowly.
- If you miss a dose of lamotrigine, 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 lamotrigine 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.
- Swallow lamotrigine tablets whole.
- If you have trouble swallowing lamotrigine tablets, tell your healthcare provider because there may be another form of lamotrigine you can take.
- If you receive lamotrigine in a blisterpack, examine the blisterpack before use. Do not use if blisters are torn, broken, or missing.

What should I avoid while taking lamotrigine?

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

What are possible side effects of lamotrigine?

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

Common side effects of lamotrigine include:

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| • dizziness | • tremor |
| • headache | • rash |
| • blurred or double vision | • fever |
| • lack of coordination | • abdominal pain |
| • sleepiness | • back pain |
| • nausea, vomiting | • tiredness |
| • insomnia | • dry mouth |

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 lamotrigine. 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 lamotrigine?

- Store lamotrigine tablets at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature] in a dry place and protect from light.
- **Keep lamotrigine and all medicines out of the reach of children.**

General information about lamotrigine

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lamotrigine for a condition for which it was not prescribed. Do not give lamotrigine 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 lamotrigine. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about lamotrigine that is written for healthcare professionals.

What are the ingredients in lamotrigine?

Active ingredient: lamotrigine USP.

Inactive ingredients: hydroxypropyl cellulose; L-hydroxypropyl cellulose; magnesium stearate; mannitol; powdered cellulose; talc; and ferric oxide.

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

To reorder additional Medication Guides, contact Dr. Reddy's Customer Service at 1-866-733-3952.

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