**MEDICATION GUIDE**

**LAMOTRIGINE TABLETS, USP**
**(la moe′ tri jeen)**
**25 mg, 100 mg, 150 mg and 200 mg**

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

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

- **Lamotrigine tablets 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 tablets, but is more likely to happen within the first 2 to 8 weeks of treatment. Children aged between 2 and 16 years have a higher chance of getting this serious skin rash while taking lamotrigine tablets.
  The risk of getting a serious skin rash is higher if you:
  1. take lamotrigine tablets while taking valproate [DEPAKENE ® (valproic acid) or DEPAKOTE ® (divalproex sodium)].
  2. take a higher starting dose of lamotrigine tablets than your healthcare provider prescribed.
  3. increase your dose of lamotrigine tablets faster than prescribed.

  **Call your healthcare provider right away if you have any of the following:**
  4. **a skin rash**
  5. **blistering or peeling of your skin**
  6. **hives**
  7. **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 tablets.
- **Other serious reactions, including serious blood problems or liver problems.** Lamotrigine tablets 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:
  8. fever
  9. frequent infections
  10. severe muscle pain
  11. swelling of your face, eyes, lips, or tongue
  12. swollen lymph glands
  13. unusual bruising or bleeding
  14. weakness, fatigue
  15. yellowing of your skin or the white part of your eyes
- **Like other antiepileptic drugs, lamotrigine tablets 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:**
  16. thoughts about suicide or dying
  17. attempt to commit suicide
  18. new or worse depression
  19. new or worse anxiety

20. feeling agitated or restless
21. panic attacks
22. trouble sleeping (insomnia)
23. new or worse irritability
24. acting aggressive, being angry, or violent
25. acting on dangerous impulses
26. an extreme increase in activity and talking (mania)
27. other unusual changes in behavior or mood

**Do not stop lamotrigine tablets without first talking to a healthcare provider.**

28. Stopping lamotrigine tablets suddenly can cause serious problems.
29. 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?**

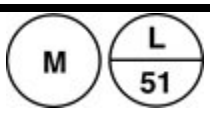
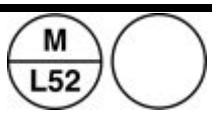
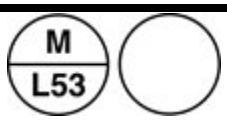
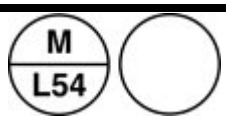
30. Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
31. Keep all follow-up visits with your healthcare provider as scheduled.
32. Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

- **Lamotrigine tablets 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:**
  33. headache
  34. fever
  35. nausea
  36. vomiting
  37. stiff neck
  38. rash
  39. unusual sensitivity to light
  40. muscle pains
  41. chills
  42. confusion
  43. drowsiness

  Meningitis has many causes other than lamotrigine tablets, which your doctor would check for if you developed meningitis while taking lamotrigine tablets.
  **Lamotrigine tablets 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 tablets?"
- **Patients prescribed lamotrigine tablets have sometimes been given the wrong medicine because many medicines have names similar to lamotrigine, so always check that you receive lamotrigine tablets.**
  Taking the wrong medication can cause serious health problems. When your healthcare provider gives you a prescription for lamotrigine tablets:
  44. Make sure you can read it clearly.
  45. Talk to your pharmacist to check that you are given the correct medicine.
  46. 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 lamotrigine tablets. Immediately call your pharmacist if you receive a lamotrigine tablet that does not look like one of the tablets shown below, as you may have received the wrong medication.

**Lamotrigine Tablets**

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|---|---|---|---|
|  **Lamotrigine Tablets** 25 mg, white to off-white debossed with **M** on one side of the tablet and **L** above the score and **51** below the score on the other side. |  **Lamotrigine Tablets** 100 mg, white to off-white debossed with **M** above the score and **L52** below the score on one side of the tablet and blank on the other side. |  **Lamotrigine Tablets** 150 mg, white to off-white debossed with **M** above the score and **L53** below the score on one side of the tablet and blank on the other side. |  **Lamotrigine Tablets** 200 mg, green debossed with **M** above the score and **L54** below the score on one side of the tablet and blank on the other side. |

**What are lamotrigine tablets?**

Lamotrigine tablets are 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 one 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 aged 18 years and older who have been treated for mood episodes with other medicine.

It is not known if lamotrigine tablets are safe or effective in children or teenagers younger than 18 years with mood disorders such as bipolar disorder or depression.

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

**Who should not take lamotrigine tablets?**

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

**What should I tell my healthcare provider before taking lamotrigine tablets?**

Before taking lamotrigine tablets, 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.
- have had aseptic meningitis after taking lamotrigine tablets.
- 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 lamotrigine tablets work.
- 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 tablets, 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 passes into breast milk and may cause side effects in a breastfed baby. If you breastfeed while taking lamotrigine tablets, watch your baby closely for trouble breathing, episodes 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 the best way to feed your baby if you take lamotrigine tablets.

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 tablets with certain other medicines, they can affect each other, causing side effects.

**How should I take lamotrigine tablets?**

- Take lamotrigine tablets 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 tablets without talking to your healthcare provider. Stopping lamotrigine tablets suddenly may cause serious problems. For example, if you have epilepsy and you stop taking lamotrigine tablets suddenly, you may have seizures that do not stop. Talk with your healthcare provider about how to stop lamotrigine tablets slowly.
- If you miss a dose of lamotrigine tablets, 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.**
- If you take too many lamotrigine tablets, call your healthcare provider or your local Poison Control Center or go to the nearest hospital emergency room right away.
- You may not feel the full effect of lamotrigine tablets 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.

**What should I avoid while taking lamotrigine tablets?**

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

**What are the possible side effects of lamotrigine tablets?**

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

Common side effects of lamotrigine tablets include:

- dizziness
- tremor
- headache
- rash
- blurred or double vision
- fever
- lack of coordination
- abdominal pain
- sleepiness
- back pain
- nausea, vomiting, diarrhea

- 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 tablets. 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 tablets?**

- Store lamotrigine tablets at 20° to 25°C (68° to 77°F).
- Protect from light and moisture.
- **Keep lamotrigine tablets and all medicines out of the reach of children.**

**General information about lamotrigine tablets**

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

If you take a urine drug screening test, lamotrigine tablets may make the test result positive for another drug. If you require a urine drug screening test, tell the healthcare professional administering the test that you are taking lamotrigine tablets.

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

For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

**What are the ingredients in lamotrigine tablets, USP?**

Active ingredient: lamotrigine, USP.

Inactive ingredients: anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch (corn) and sodium lauryl sulfate. In addition, the 200 mg tablets contain D&C Yellow No. 10 Aluminum Lake and FD&C Blue No. 1 Aluminum Lake.

*The brands listed are trademarks of their respective owners.

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

Manufactured by:
**Mylan Pharmaceuticals Inc.**
Morgantown, WV 26505 U.S.A.

Distributed by:
**Mylan Institutional Inc.**
Rockford, IL 61103 U.S.A.

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