

MEDICATION GUIDE

LAMICTAL[®] (la-MIK-tal) (lamotrigine) tablets

LAMICTAL[®] (lamotrigine) chewable dispersible tablets

LAMICTAL ODT[®] (lamotrigine) orally disintegrating tablets

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

1. **LAMICTAL 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 LAMICTAL, 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 LAMICTAL.

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

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

1. **Other serious reactions, including serious blood problems or liver problems.** LAMICTAL 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:
2. fever
3. frequent infections
4. severe muscle pain
5. swelling of your face, eyes, lips, or tongue
6. swollen lymph glands
7. unusual bruising or bleeding
8. weakness, fatigue
9. yellowing of your skin or the white part of your eyes
10. **Like other antiepileptic drugs, LAMICTAL 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:

11. thoughts about suicide or dying
12. attempt to commit suicide
13. new or worse depression
14. new or worse anxiety
15. feeling agitated or restless
16. panic attacks
17. trouble sleeping (insomnia)
18. new or worse irritability
19. acting aggressive, being angry, or violent
20. acting on dangerous impulses
21. an extreme increase in activity and talking (mania)
22. other unusual changes in behavior or mood

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

- Stopping LAMICTAL 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 in myself or a family member?

- 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 may 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 LAMICTAL, which your doctor would check for if you developed meningitis while taking LAMICTAL.

LAMICTAL can cause 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?”





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

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




- 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 tablets, chewable dispersible tablets, and orally disintegrating tablets. Immediately call your pharmacist if you receive a LAMICTAL tablet that does not look like one of the tablets shown below, as you may have received the wrong medication.





LAMICTAL (lamotrigine) tablets

 25 mg, white Imprinted with LAMICTAL 25	 100 mg, peach Imprinted with LAMICTAL 100	 150 mg, cream Imprinted with LAMICTAL 150	 200 mg, blue Imprinted with LAMICTAL 200
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LAMICTAL (lamotrigine) chewable dispersible tablets

 2 mg, white Imprinted with LTG 2	 5 mg, white Imprinted with GX CL2	 25 mg, white Imprinted with GX CL5
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LAMICTAL ODT (lamotrigine) orally disintegrating tablets

 25 mg, white to off-white Imprinted with LMT on one side 25 on the other	 50 mg, white to off-white Imprinted with LMT on one side 50 on the other	 100 mg, white to off-white Imprinted with LAMICTAL on one side 100 on the other	 200 mg, white to off-white Imprinted with LAMICTAL on one side 200 on the other
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What is LAMICTAL?

LAMICTAL 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.

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

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

It is not known if LAMICTAL is safe or effective for people with mood episodes who have not already been treated with other medicines.

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

Who should not take LAMICTAL?

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

What should I tell my healthcare provider before taking LAMICTAL?

Before taking LAMICTAL, 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 LAMICTAL or LAMICTAL XR (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 LAMICTAL may cause side effects (such as dizziness, lack of coordination, or double vision). Starting these medicines may lessen how well LAMICTAL works.
- are pregnant or plan to become pregnant. It is not known if LAMICTAL will harm your unborn baby. If you become pregnant while taking LAMICTAL, 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 passes into breast milk and may cause side effects in a breastfed baby. If you breastfeed while taking LAMICTAL, 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 LAMICTAL.

Tell your healthcare provider about all the medicines you take or if you are planning to take a new medicine, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

If you use LAMICTAL with certain other medicines, they can affect each other, causing side effects.

How should I take LAMICTAL?

- Take LAMICTAL 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 without talking to your healthcare provider. Stopping LAMICTAL suddenly may cause serious problems. For example, if you have epilepsy and you stop taking LAMICTAL suddenly, you may have seizures that do not stop. Talk with your healthcare provider about how to stop LAMICTAL slowly.
- If you miss a dose of LAMICTAL, 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 2 doses at the same time.**
- If you take too much LAMICTAL, 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 LAMICTAL 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 LAMICTAL Tablets whole.
- If you have trouble swallowing LAMICTAL Tablets, tell your healthcare provider because there may be another form of LAMICTAL you can take.
- LAMICTAL ODT should be placed on the tongue and moved around the mouth. The tablet will rapidly disintegrate, can be swallowed with or without water, and can be taken with or without food.
- LAMICTAL chewable dispersible tablets may be swallowed whole, chewed, or mixed in water or fruit juice mixed with water. If the tablets are chewed, drink a small amount of water or fruit juice mixed with water to help in swallowing. To break up LAMICTAL chewable dispersible tablets, add the tablets to a small amount of liquid (1 teaspoon, or enough to cover the medicine) in a glass or spoon. Wait at least 1 minute or until the tablets are completely broken up, mix the solution together, and take the whole amount right away.
- If you receive LAMICTAL 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?

Do not drive, operate machinery, or do other dangerous activities until you know how LAMICTAL affects you.

What are the possible side effects of LAMICTAL?

LAMICTAL can cause serious side effects.

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

Common side effects of LAMICTAL include:

- dizziness
- tremor
- headache
- rash
- blurred or double vision
- fever
- lack of coordination
- abdominal pain
- infections, including seasonal flu

- sleepiness
- back pain
- nausea, vomiting
- diarrhea
- tiredness
- insomnia
- dry mouth
- stuffy nose
- sore throat

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. 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?

- Store LAMICTAL at room temperature between 68°F and 77°F (20°C and 25°C).
- **Keep LAMICTAL and all medicines out of the reach of children.**

General information about the safe and effective use of LAMICTAL.

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

If you take a urine drug screening test, LAMICTAL 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 LAMICTAL.

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

For more information, call 1-888-825-5249.

What are the ingredients in LAMICTAL?

LAMICTAL tablets

Active ingredient: lamotrigine.

Inactive ingredients: lactose; magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate, FD&C Yellow No. 6 Lake (100-mg tablet only), ferric oxide, yellow (150-mg tablet only), and FD&C Blue No. 2 Lake (200-mg tablet only).

LAMICTAL chewable dispersible tablets

Active ingredient: lamotrigine.

Inactive ingredients: blackcurrant flavor, calcium carbonate, low-substituted hydroxypropylcellulose, magnesium aluminum silicate, magnesium stearate, povidone, saccharin sodium, and sodium starch glycolate.

LAMICTAL ODT orally disintegrating tablets

Active ingredient: lamotrigine.

Inactive ingredients: artificial cherry flavor, crospovidone, ethylcellulose, magnesium stearate, mannitol, polyethylene, and sucralose.

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

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Distributed by

GlaxoSmithKline

Research Triangle Park, NC 27709

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December 2016

LMT:15MG