MEDICATION GUIDE

Lamotrigine orally disintegrating tablet

(lă-mō'trī-jēn)

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

1. Lamotrigine orally disintegrating 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 orally disintegrating tablets, 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 orally disintegrating tablets.

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

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

2. Other serious reactions, including serious blood problems or liver problems. Lamotrigine orally disintegrating 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:

- 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 orally disintegrating 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:

- 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 orally disintegrating tablets without first talking to a healthcare provider.

- Stopping lamotrigine orally disintegrating tablets 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.

4. Lamotrigine orally disintegrating 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:

- headache
- fever
- nausea
- vomiting
- stiff neck
- rash
- unusual sensitivity to light
- muscle pains
- chills
- confusion
- drowsiness

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

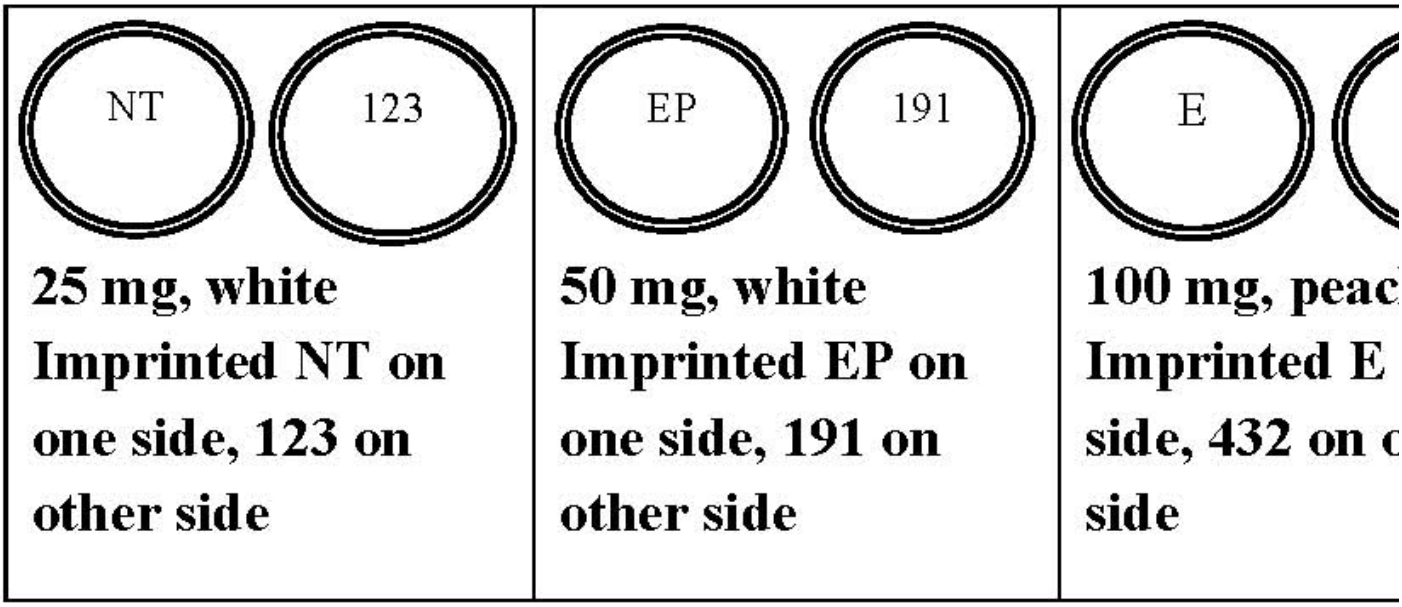
Lamotrigine orally disintegrating tablets can cause other serious side effects. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you. Be sure to read the section below entitled “What are the possible side effects of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

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

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

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



What is lamotrigine orally disintegrating tablets?

Lamotrigineorally disintegrating tablets 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 lamotrigine orally disintegrating tablets is safe or effective in people younger than 18 years with mood episodes such as bipolar disorder or depression.

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

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

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

Who should not take lamotrigine orally disintegrating tablets?

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

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

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

· are pregnant or plan to become pregnant. It is not known if lamotrigine orally disintegrating tablets will harm your unborn baby. If you become pregnant while taking lamotrigine orally disintegrating 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 orally disintegrating 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 orally disintegrating tablets.

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

How should I take lamotrigine orally disintegrating tablets?

· Take lamotrigine orally disintegrating 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 orally disintegrating tablets without talking to your healthcare provider. Stopping lamotrigine orally disintegrating tablets suddenly may cause serious problems. For example, if you have epilepsy and you stop taking lamotrigine orally disintegrating tablets suddenly, you may have seizures that do not stop. Talk with your healthcare provider about how to stop lamotrigine orally disintegrating tablets slowly.

· If you miss a dose of lamotrigine orally disintegrating 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 2 doses at the same time.**

· If you take too much lamotrigine orally disintegrating 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 orally disintegrating 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.

· Lamotrigine 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.

· If you receive lamotrigine orally disintegrating tablets 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 orally disintegrating tablets?

Do not drive, operate machinery, or do other dangerous activities until you know how lamotrigine orally disintegrating tablets affects you.

What are the possible side effects of lamotrigine orally disintegrating tablets?

Lamotrigine orally disintegrating tablets can cause serious side effects.

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

Common side effects of lamotrigine orally disintegrating tablets 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 lamotrigine orally disintegrating 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 orally disintegrating tablets?

- Store lamotrigine orally disintegrating tablets at room temperature between 20°C to 25°C (68°F to 77°F); with excursions permitted to15°C to 30°C (59°F to 86°F). [see USP Controlled Room Temperature].
- **Keep lamotrigine orally disintegrating tablets and all medicines out of the reach of children.**

General information about the safe and effective use of lamotrigine orally disintegrating tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lamotrigine orally disintegrating tablets for a condition for which it was not prescribed. Do not give lamotrigine orally disintegrating 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 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 orally disintegrating tablets.

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

What are the ingredients in lamotrigine orally disintegrating tablets?

Active ingredient: Lamotrigine

Inactive Ingredients:

For lamotrigine orally disintegrating tablets 25 mg, 50 mg and 200 mg: Colloidal silicon di-oxide, croscarmellose sodium, magnesium stearate, mannitol, starch (maize), microcrystalline cellulose, peppermint flavor, sodium stearyl fumarate, and sucralose.

For lamotrigine orally disintegrating tablets 100 mg: Colloidal silicon di-oxide, croscarmellose sodium, magnesium stearate, mannitol, starch (maize), microcrystalline cellulose, peppermint flavor, sodium stearyl fumarate, sucralose and idacol red oxide of iron.

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

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