

LAMICTAL[®]ODT[™] (LAMOTRIGINE) ORALLY DISINTEGRATING TABLETS

For patients TAKING valproate*

*Includes valproic acid and divalproex sodium.

R_x only

Instructions:

For weeks 1 and 2, take one 25 mg tablet EVERY other DAY.

WEEK 1

25	Day 1
NONE	Day 2
25	Day 3
NONE	Day 4
25	Day 5
NONE	Day 6
25	Day 7

WEEK 2

NONE	Day 8
25	Day 9
NONE	Day 10
25	Day 11
NONE	Day 12
25	Day 13
NONE	Day 14

Instructions:

For weeks 3 and 4, take one 25 mg tablet ONCE a DAY.

WEEK 3

25	Day 15
25	Day 16
25	Day 17
25	Day 18
25	Day 19
25	Day 20
25	Day 21

WEEK 4

25	Day 22
25	Day 23
25	Day 24
25	Day 25
25	Day 26
25	Day 27
25	Day 28

Instructions:

For week 5, take one 50 mg tablet ONCE a DAY.

WEEK 5

50	Day 29
50	Day 30
50	Day 31
50	Day 32
50	Day 33
50	Day 34
50	Day 35

Weeks	Tablets per day
1 & 2	Take 1 (25 mg) tablet every <u>OTHER</u> day
3 & 4	Take 1 (25 mg) tablet once a day
5	Take 1 (50 mg) tablet once a day

Store between 20°C to 25°C (68°F to 77°F); with excursions permitted between 15°C to 30°C (59°F to 86°F).

Keep this and all medicines out of the reach of children.

Do not use if blisters are torn, broken, or missing.

CAUTION:
Verify Product Dispensed

When your healthcare provider gives you a prescription for LAMICTAL ODT, make sure that the tablets in the kit you receive are the same color (white) and have the same markings (25 and 50) as the tablets on this page.

To avoid missed days of treatment check with your doctor for dosing instructions prior to week 5. Please check with your physician about proper maintenance dose before week 5.

Please carefully read the Important Safety Information and Medication Guide on the following pages before you take LAMICTAL ODT. Please read the Medication Guide provided with any refill, in case any information has changed. The Medication Guide provides a summary of the information about your medicine. Please do not throw away this Guide until you have finished your medicine. This Guide does not contain all the information about LAMICTAL ODT and is not meant to take the place of talking with your doctor. If you have any questions about LAMICTAL ODT, ask your doctor or pharmacist.

Physician Instructions: _____

LAMICTAL[®] ODT[™] (lamotrigine) Orally Disintegrating Tablets

25 mg, 100 mg, 150 mg, 200 mg

Prescription LAMICTAL ODT is not for everyone.

LAMICTAL ODT 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 or (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 LAMICTAL ODT 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 LAMICTAL ODT is safe or effective when used alone as the first treatment of seizures in adults.

IMPORTANT SAFETY INFORMATION FOR LAMICTAL ODT (lamotrigine) Orally Disintegrating Tablets

LAMICTAL ODT is another form of LAMICTAL.

LAMICTAL may cause a serious skin rash that may cause you to be hospitalized or to stop LAMICTAL; it may rarely cause death.

There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when you begin taking LAMICTAL, within the first 2 to 8 weeks of treatment. But it can happen in people who have taken LAMICTAL for any period of time. Children between 2 to 16 years of age have a higher chance of getting this serious skin reaction while taking LAMICTAL.

The risk of getting a 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.

LAMICTAL can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the 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 the following:

- a skin rash
- hives
- fever
- swollen lymph glands
- painful sores in the mouth or around your eyes
- swelling of your lips or tongue
- yellowing of your skin or eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections

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

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 worsening depression, any unusual changes in mood or behavior, or thoughts or actions about suicide or self-harm, especially if they are new, worse, or worry you (see Medication Guide on next page).

You should not take LAMICTAL if you have had an allergic reaction to lamotrigine or to any of the inactive ingredients.

Common side effects include:

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

Tell your healthcare provider about any side effect that bothers you or does not go away. Also, tell your healthcare provider if you have any changes in your menstrual pattern, such as breakthrough bleeding, while taking LAMICTAL and birth control pills. These are not all the possible side effects of LAMICTAL.

Patients 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 in the Medication Guide on the next page.

*DEPAKENE and DEPAKOTE are registered trademarks of Abbott Laboratories.

Please see Medication Guide on following pages.



MEDICATION GUIDE

LAMICTAL® (la-MIK-tal) (lamotrigine) Tablets and Chewable Dispersible Tablets

LAMICTAL® ODT™ (lamotrigine) Orally Disintegrating Tablets

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

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 to stop LAMICTAL; it may rarely cause death.

There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when you begin taking LAMICTAL, within the first 2 to 8 weeks of treatment. But it can happen in people who have taken LAMICTAL for any period of time. Children between 2 to 16 years of age have a higher chance of getting this serious skin reaction while taking LAMICTAL.

The risk of getting a 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.

LAMICTAL can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the 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 the following:

- a skin rash
- hives
- fever
- swollen lymph glands
- painful sores in the mouth or around your eyes
- swelling of your lips or tongue
- yellowing of your skin or eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections

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

2. 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:

- 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 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?

- 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 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 LAMICTAL?"

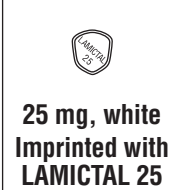


3. Patients prescribed LAMICTAL have sometimes been given the wrong medicine because many medicines have names similar to LAMICTAL, so always check that you receive LAMICTAL.

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

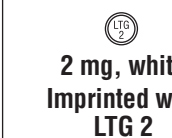
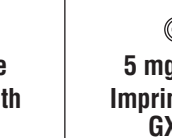
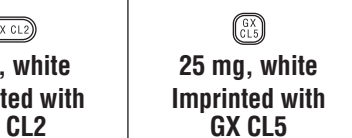
- Make sure you can read it clearly.
- Talk to your pharmacist to check that you are given the correct medicine.
- Each time you fill your prescription, check the tablets you receive against the pictures of the tablets below.

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.

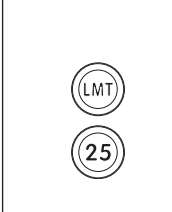
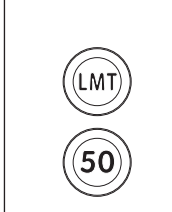
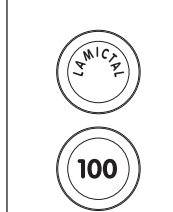
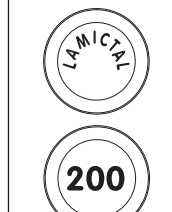
LAMICTAL (lamotrigine) Tablets

			
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

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

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

LAMICTAL® (lamotrigine) Tablets and Chewable Dispersible Tablets LAMICTAL® ODT™ (lamotrigine) Orally Disintegrating Tablets

What is LAMICTAL?

LAMICTAL 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 LAMICTAL 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 LAMICTAL is safe or effective when used alone as the first treatment of seizures in adults.

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.
- 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 or starting these medicines may cause side effects (such as dizziness, lack of coordination, or double vision) or 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 can pass into your breast milk. You and your healthcare provider should decide if you should take LAMICTAL or breastfeed. Breastfeeding while taking LAMICTAL 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. Using LAMICTAL with certain other medicines 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 get 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 two doses at the same time.**
- 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, 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 diluted fruit juice. If the tablets are chewed, drink a small amount of water or diluted fruit juice 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 a car or operate complex, hazardous machinery until you know how LAMICTAL affects you.

What are possible side effects of LAMICTAL?

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

Common side effects of LAMICTAL include:

- dizziness
- headache
- blurred or double vision
- lack of coordination
- sleepiness
- nausea, vomiting
- insomnia
- tremor
- rash
- fever
- abdominal pain
- back pain
- tiredness
- 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 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 to 77°F (20°C to 25°C).
- **Keep LAMICTAL and all medicines out of the reach of children.**

General information about 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.

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, go to www.lamictal.com or 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.

LAMICTAL® (lamotrigine) Tablets and Chewable Dispersible Tablets
LAMICTAL® ODT™ (lamotrigine) Orally Disintegrating Tablets

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.



GlaxoSmithKline
Research Triangle Park, NC 27709

LAMICTAL Tablets and Chewable Dispersible Tablets are manufactured by DSM Pharmaceuticals, Inc., Greenville, NC 27834 or GlaxoSmithKline Research Triangle Park, NC 27709

LAMICTAL Orally Disintegrating Tablets are manufactured by Eurand, Inc., Vandalia, OH 45377

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