

## Lamictal® (lamotrigine)

**Important Warning :** Serious skin rashes requiring medical hospitalization and discontinuation of treatment have been associated with Lamictal. Although rare, this rash (also known as Stevens– Johnson Syndrome) can be life threatening. Any patient who develops a rash while taking Lamictal (or any other medication) should report this to their doctor quickly. People who may be at a higher risk for this rash are those who are also taking Depakene or Depakote, those who have their Lamictal doses increased rapidly, and those patients who are younger than 16 years.

**FDA Alert (9/2006)** New information suggests that babies exposed to Lamictal during the first three months of pregnancy may have a higher chance of being born with a cleft lip or cleft palate. Babies born with cleft lip or cleft palate have a gap in the upper lip or roof of the mouth. If you take Lamictal and are pregnant or are thinking of becoming pregnant, talk with your doctor. Lamictal is used for seizures or bipolar disorder, serious conditions that need treatment even during pregnancy. Do not start or stop using Lamictal without talking to your doctor. More research is needed to be sure about this possibly increased chance of cleft lip or cleft palate in babies born to mothers who take Lamictal.

**Note: It is very important to check your medication each time it is filled. There have been errors reported in consumers receiving Lamisil instead of Lamictal.**

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### Brand and Generic Names

- Brand name: Lamictal

Tablets (non–chewable): 25 mg, 100 mg, 150 mg, 200 mg

Chewable tablets: 2 mg, 5 mg, 25 mg

Two different dosing "starter" kits are also available. One is for patients who are already taking valproate (Depakote®); the other is for patients who are already taking carbamazepine (Tegretol®).

- Generic name: lamotrigine (la MOE tri jeen)

### **What is Lamictal® and what does it treat?**

Lamotrigine is an anticonvulsant drug approved for the treatment of seizures (epilepsy) in adults and children. It can be used alone, or in combination with other anticonvulsants. It has also been approved for the maintenance treatment of bipolar disorder (manic-depressive disorder). That means lamotrigine will help to delay the time to occurrence of mood episodes. Some patients with rapid-cycling bipolar disorder (four or more mood episodes in one year) have been treated with lamotrigine by itself.

Bipolar disorder is a brain disorder (mental illness) that exposes people to these mood changes over the course of time. Bipolar disorder affects more than two million American each year, but patients with this disorder can lead fulfilling lives when they receive proper treatment. Unfortunately, many people with this illness do not receive treatment.

Bipolar disorder involves episodes of depression and/or mania. A depressive episode, or depression, is when a person experiences several of the following symptoms at the same time: “low” or depressed mood (for example, sad, empty, tearful), decreased interest in most or all activities, changes in appetite (usually decreased), changes in sleep (usually poor sleep), loss of energy, feeling worthless/guilty/ hopeless/ helpless, difficulty concentrating, thoughts of death (suicidal thinking). Lamotrigine has been studied for the treatment of bipolar depression.

A manic episode, or mania, is when a person experiences several of the following symptoms at the same time: “high” or irritable mood, very high self esteem, decreased need for sleep, pressure to keep talking, racing thoughts, being easily distracted, frequently involved in activities with a large risk for bad consequences (for example, excessive buying sprees). Lamotrigine by itself has not been useful for severe or recurrent mania.

### **What is the most important information I should know about Lamictal®?**

Since bipolar disorder is a long-term illness, duration of treatment with mood stabilizers like lamotrigine may also be long-term. It is very important to take Lamictal regularly and exactly as prescribed by your doctor. Missing doses of lamotrigine increases your risk for a relapse in your mood symptoms. It may also increase the possibilities of troublesome side effects such as seizures.

Do not stop taking lamotrigine or change your dose without talking to with your healthcare provider first.

In order for lamotrigine to work properly, it should be taken every day as ordered by your health care provider.

- Lamotrigine may be prescribed by itself or along with other medications to manage your mood symptoms.
- Compared to lithium and valproic acid, lamotrigine may not be as effective in stabilizing a manic episode, however, it may be more effective in treating depressive episodes experienced by individuals with bipolar disorder.
- Similar to lithium and valproate lamotrigine has demonstrated effectiveness in preventing relapses of depression and mania when taken daily as prescribed.
- Lamotrigine can be associated with serious skin rashes, which are rare. If you experience a new rash while taking lamotrigine, call your doctor immediately.
- Bipolar disorder is an illness that may have suicidal thinking as a possible symptom. You should report any new occurrence, or worsening, of suicidal thinking to your doctor.
- Note: It is very important to check your medication at the pharmacy each time it is filled. There have been pharmacy dispensing errors reported with consumers receiving “Lamisil<sup>®</sup>” instead of “Lamictal<sup>®</sup>”. Lamisil<sup>®</sup> is a medication that is used for the treatment of fungal infections of the toenails or fingernails .

### **Are There specific concerns about Lamictal<sup>®</sup> and pregnancy?**

Lamotrigine can interfere with folic acid. Therefore, female patients should be aware that lamotrigine may increase the chances of birth defects in babies. New information suggests that babies exposed to lamotrigine during the first three months of pregnancy may have a higher chance of being born with a cleft lip or cleft palate. Babies born with cleft lip or cleft palate have a gap in the upper lip or roof of the mouth. More research is needed to be sure about this possibly increased chance of cleft lip or cleft palate in babies born to mothers who take lamotrigine.

If you are planning on becoming pregnant or have become pregnant, you should talk with your healthcare provider so that he/she can best manage your medications. People living with bipolar disorder who wish to become pregnant face important decisions about the risks and benefits of the medications as they relate to the illness, and to the fetus. This is a complex decision as untreated bipolar disorder has risks to the fetus as well as the mother. There are many dimensions to these choices, so be sure to confer with your doctor and caregivers. Do not start or stop taking lamotrigine without talking to your doctor.

Due to a lack of data to ensure safety, breast feeding while taking lamotrigine is not recommended.

### **What should I discuss with my healthcare provider before taking Lamictal<sup>®</sup>?**

- You should tell your doctor if you have taken Lamictal before and if you are allergic to it. You should also tell your doctor and pharmacist exactly what the medication did to you before taking even one dose. In addition, you should discuss the following:

- Medications you have taken in the past to treat bipolar disorder, whether they were effective or caused any adverse effects
- Symptoms which are most bothersome to you about your condition
- Any medical problems you may have, especially kidney disease
- All other medications you are currently taking, and any medication allergies you have
- If you smoke, drink alcohol, or use illegal drugs
- If you have thoughts of suicide
- If you are pregnant, plan to become pregnant, or are breast-feeding

**How should I take Lamictal®?**

The amount of lamotrigine you take, and how quickly your dose will increase depends on whether or not you are taking other medications that may interact with lamotrigine. The table that follows provides important information about dosing. The maximum lamotrigine dose in the treatment of Bipolar disorder is different depending on other medications you are taking. Your healthcare provider will determine the dose that is right for you based upon your response

*Schedule of lamotrigine dose increases in patients being treated for bipolar disorder.*

<b>Duration of Treatment</b>	<b>No Other Interacting Meds</b>	<b>For Patients Taking Depakote</b>	<b>For Patients Taking Tegretol</b>
Weeks 1 & 2	25 mg daily	25 mg every other day	50 mg daily
Weeks 3 & 4	50 mg daily	25 mg daily	100 mg daily (in divided doses)
Week 5	100 mg daily	50 mg daily	200 mg daily (in divided doses)
Week 6	200 mg daily	100 mg daily	300 mg daily (in divided doses)
Week 7	200 mg daily	100 mg daily	Up to 400 mg daily (in divided doses)

- Lamotrigine may be taken with food to minimize stomach cramping, nausea, and vomiting.
- Always take lamotrigine at the same time every day
- Use a pillbox or a calendar as a reminder to take your medications. If needed, have a family member or friend check-in with you to help you take your medications.

### **What happens if I miss a dose of Lamictal®?**

If you miss a dose of lamotrigine, take it as soon as you remember to, but only if it is not too close to when your next dose is due - discuss this with your healthcare provider. If it is close to your next dose, wait until then to take the medication and skip the missed dose. Do not double your next dose or take more than what you have been told to take.

### **What should I avoid while taking lamictal®?**

- Avoid drinking alcohol while taking lamotrigine because it can increase the effects of alcohol and lead to significant drowsiness.
- Avoid using illegal drugs while taking lamotrigine because the beneficial effects of the medication may be decreased and adverse effects (e.g. sedation) and risk of seizures may be increased.
- As lamotrigine may cause drowsiness, make sure you know how it will affect you before you begin driving or operating any machinery.

### **What happens if I overdose?**

If an overdose occurs, whether intentional or accidental, immediate medical attention may be necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).

There have been reports of people who have overdosed with lamotrigine. Some of the overdoses resulted in death. Overdose has resulted in dizziness, abnormal eye movements, seizures, sleepiness or loss of consciousness, and abnormal heart rhythms.

A specific antidote for lamotrigine does not exist.

### **What are the possible side effects of Lamictal®?**

Patients being treated with lamotrigine for bipolar disorder should report to their doctor if suicidal thinking starts or worsens. They should also report to their doctor if their mood symptoms begin to “switch” from symptoms of depression to symptoms of mania.

Common side effects reported by people who have taken lamotrigine alone for the treatment of bipolar disorder include: nausea, insomnia, daytime sleepiness, feeling physically tired (fatigue), runny nose, and non-serious rash.

Common side effects reported by people who were taking lamotrigine in combination with another treatment or treatments for bipolar disorder include: headache, rash, dizziness, diarrhea, abnormal dreams, and itchy skin.

A serious, life threatening rash (also known as Stevens–Johnson Syndrome) may occur with the use of lamotrigine. Although this rash is believed to be rare, any patient who develops a rash while taking lamotrigine (or any other medication) should report this to

their doctor quickly. Extra caution is needed in patients who are younger than the age of 16 and receiving lamotrigine - these patients may be at an increased risk of developing this life threatening rash. Other rare, but serious, side effects may occur with lamotrigine. Talk with your healthcare provider if you experience side effects that are bothersome.

Seizures may occur if a patient taking lamotrigine suddenly stops taking it.

### **Are there any risks for taking Lamictal® for long periods of time?**

None are known, however, lamotrigine is meant to be taken for a long time. In fact, you should not suddenly stop taking lamotrigine without talking to your doctor first .

### **What other drugs interact with lamictal®?**

- Medications that may increase levels of lamotrigine in your body: valproic acid/valproate/divalproex (Depakene®/Depakote®/Depakote ER®), efavirenz (Sustiva®), delavirdine (Rescriptor®).
- Medications that may decrease levels of lamotrigine in your body: carbamazepine (Tegretol®), ethinyl estradiol/levonorgestrel (multiple brand names): Alesse®, Aviane®, Enpresse®, Lessina-28®, Levlen®, Levlite®, Levora®, Nordette®, Portia®, Seasonale®, Tri-Levlen®, Triphasil®, Trivora-28®, phenytoin (Dilantin®), rifampin (Rifadin®), ritonavir (Norvir®), nevirapine (Viramune®).
- Clozapine blood levels may become too high, or “toxic”, when lamotrigine therapy is added.

### **How long does it take for Lamictal® to work?**

It is very important to tell your doctor how you feel things are going during the first two months after you start taking lamotrigine, or after your dose has been changed. It will probably take several weeks for you and your doctor to see enough changes in your symptoms to decide if lamotrigine is the right drug for you.

Mood stabilizer treatment is generally needed lifelong for persons with bipolar illness. Your doctor can best discuss the duration of treatment you need based on your symptoms and course of illness

*Updated by Charles F. Caley, Pharm.D., BCPP  
(June 2007)*



NAMI wishes to thank the [College of Psychiatric and Neurological Pharmacists](#) for producing this fact sheet.

*Reviewed by Dr. Ken Duckworth, NAMI Medical Director*

**For further information. Please contact the pharmaceutical company listed below.**

GlaxoSmithKline Bridges to Access	Bridges to Access PO Box 29038 Phoenix, AZ 85038-9038	1-866-728- 4368	<a href="http://bridgestoaccess.gsk.com/">http://bridgestoaccess.gsk.com/</a>
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**Free or low-cost medications provided by pharmaceutical companies**

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

**Lamictal Rx Assistance Program:** 1-866-728-4368