

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**ANDA 090170**

**LABELING**



<p>Each scored tablet contains <b>25 mg of lamotrigine USP.</b> See package insert for Dosage and Administration. <b>Store at 20°-25° C (68°-77° F) [See USP Controlled Room Temperature] in a dry place.</b> Dispense in a tight, light-resistant container as defined in the USP. <b>CAUTION - Verify Product Dispensed.</b></p>	<p>NDC 29300-111-01 <b>LAMOTRIGINE TABLETS USP</b></p>	<p>M.L. 321</p>
 <p>N 31 29300111101 9</p>	<p><b>25 mg</b> Rx Only <b>100 Tablets</b> <b>ATTENTION PHARMACIST :</b> Each patient is required to receive the accompanying Medication Guide <b>UNICHEM</b></p>	<p>Lot : Exp.: Manufactured by: <b>UNICHEM LABORATORIES LTD.</b> Pijerne Ind. Estate, Pijerne, Bardez, Goa 403 511, India Marketed by :  <b>UNICHEM</b> PHARMACEUTICALS (USA), INC. Rochelle Park, NJ 07662.</p>



Each scored tablet contains  
**25 mg of lamotrigine USP.**  
See package insert for Dosage  
and Administration.  
**Store at 20°-25°C (68°-77°F)**  
**[See USP Controlled Room  
Temperature] in a dry place.**  
Dispense in a tight, light-resistant  
container as defined in the USP.  
**CAUTION : Verify Product Dispensed.**

**NDC 29300-111-05**

**LAMOTRIGINE  
TABLETS USP**

**25 mg**

**Rx Only**

**500 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

M.L. 321  
Lot :  
Exp.:

Manufactured by:  
**UNICHEM LABORATORIES LTD.**  
Pierne Ind. Estate, Pierne, Bardez,  
Goa 403 511, India

Marketed by :  
 **UNICHEM**  
PHARMACEUTICALS (USA), INC.  
Rochelle Park, NJ 07662.

13002688  
R-02-07/2011



N  
3 1 2 9 3 0 0 1 1 1 0 5 1 7

(b) (4)

Each scored tablet contains  
**25 mg of lamotrigine USP.**  
See package insert for Dosage  
and Administration.  
**Store at 20°-25°C (68°-77°F)**  
**[See USP Controlled Room**  
**Temperature] in a dry place.**  
Dispense in a tight, light-resistant  
container as defined in the USP.  
**CAUTION : Verify Product Dispensed.**



13002689  
R-02-07/2011

NDC 29300-111-10  
**LAMOTRIGINE  
TABLETS USP**

**25 mg**

**Rx Only**

**1000 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

M.L. 321

Lot :

Exp.:

Manufactured by:  
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Pilerne Ind. Estate, Pilerne, Bardez,  
Goa 403 511, India

Marketed by :



**UNICHEM**  
**PHARMACEUTICALS (USA). INC.**

Rochelle Park, NJ 07662.



Each scored tablet contains  
**100 mg of lamotrigine USP.**  
See package insert for Dosage  
and Administration.  
**Store at 20°-25°C (68°-77°F)**  
[See USP Controlled Room  
Temperature] in a dry place.  
Dispense in a tight, light-resistant  
container as defined in the USP.  
**CAUTION** : Verify Product Dispensed.

**NDC 29300-112-01**

**LAMOTRIGINE  
TABLETS USP**

**100 mg**

**Rx Only**  
**100 Tablets**

**ATTENTION PHARMACIST :**  
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accompanying Medication Guide

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M.L. 321  
Lot :  
Exp.:

Manufactured by:  
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Goa 403 511, India

Marketed by :  
 **UNICHEM**  
PHARMACEUTICALS (USA) INC.  
Rochelle Park, NJ 07662.

  
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P-02-07/2011

(b) (4)

Each scored tablet contains  
**100 mg of lamotrigine USP.**  
See package insert for  
Dosage and Administration.  
**Store at 20°-25°C (68°-77°F)**  
[See USP Controlled Room  
Temperature] in a dry place.  
Dispense in a tight,  
light-resistant container  
as defined in the USP.  
**CAUTION :**  
Verify Product Dispensed.

**NDC 29300-112-05** M.L. 321  
**LAMOTRIGINE** Lot :  
**TABLETS USP** Exp.:

**100 mg**  
**Rx Only**  
**500 Tablets**

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Bardez, Goa 403 511, India

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PHARMACEUTICALS (USA) INC.  
Rochelle Park, NJ 07662.

13002891  
R402-07/2011



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31 2 9 3 0 0 1 1 1 2 0 5 1 4

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide  
**UNICHEM**

(b) (4)

Each scored tablet contains  
100 mg of lamotrigine USP.  
See package insert for  
Dosage and Administration.  
Store at 20°-25°C (68°-77°F)  
[See USP Controlled Room  
Temperature] in a dry place.

Dispense in a tight,  
light-resistant container  
as defined in the USP.

**CAUTION :**  
Verify Product Dispensed.



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R-02-07/2011

NDC 29300-112-10

M.L. 321

# LAMOTRIGINE TABLETS USP

Lot :

Exp.:

**100 mg**

**Rx Only**

**1000 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

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Pilerne Ind. Estate, Pilerne,  
Bardez, Goa 403 511, India

Marketed by :



**UNICHEM**  
PHARMACEUTICALS (USA). INC.

Rochelle Park, NJ 07662.



Each scored tablet contains  
**150 mg of lamotrigine USP.**  
See package insert for Dosage  
and Administration.  
**Store at 20°-25° C (68°-77° F)**  
**[See USP Controlled Room  
Temperature] in a dry place.**  
Dispense in a tight, light-resistant  
container as defined in the USP.  
**CAUTION : Verify Product Dispensed.**

**NDC 29300-113-16**

**LAMOTRIGINE  
TABLETS USP**

**150 mg**

**Rx Only**

**60 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

M.L. 321

Lot :

Exp.:

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Marketed by :

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PHARMACEUTICALS (USA), INC.  
Rochelle Park, NJ 07662.

13002989  
R402-07/2011

N  
31 293001131617

(b) (4)

Each scored tablet contains  
**150 mg of lamotrigine USP.**  
See package insert for  
Dosage and Administration.  
**Store at 20°-25°C (68°-77°F)**  
[See USP Controlled Room  
Temperature] in a dry place.

Dispense in a tight,  
light-resistant container as  
defined in the USP.

**CAUTION :**  
Verify Product Dispensed.



13002694  
R-02-07/2011

NDC 29300-113-05

M.L. 321

# LAMOTRIGINE TABLETS USP

Lot :

Exp.:

**150 mg**

**Rx Only**

**500 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

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**UNICHEM LABORATORIES LTD.**  
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Goa 403 511, India

Marketed by :



**UNICHEM**  
PHARMACEUTICALS (USA), INC.

Rochelle Park, NJ 07662.

(b) (4)

Each scored tablet contains  
**150 mg of lamotrigine USP.**  
See package insert for  
Dosage and Administration.  
**Store at 20°-25°C (68°-77°F)**  
**[See USP Controlled Room**  
**Temperature] in a dry place.**  
Dispense in a tight,  
light-resistant container  
as defined in the USP.  
**CAUTION :**  
Verify Product Dispensed.



13002695  
R-02-07/2011

NDC 29300-113-10

# LAMOTRIGINE TABLETS USP

**150 mg**

**Rx Only**

**1000 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

M.L. 321

Lot :

Exp.:

Manufactured by:  
**UNICHEM LABORATORIES LTD.**  
Pilerne Ind. Estate, Pilerne,  
Bardez, Goa 403 511, India

Marketed by :



**UNICHEM**  
PHARMACEUTICALS (USA), INC.

Rochelle Park, NJ 07662.



Each scored tablet contains  
**200 mg of lamotrigine USP.**  
See package insert for Dosage  
and Administration.  
**Store at 20°-25° C (68°-77° F)**  
[See USP Controlled Room  
Temperature] in a dry place.  
Dispense in a tight, light-resistant  
container as defined in the USP.  
**CAUTION : Verify Product Dispensed.**

**NDC 29300-114-16**

**LAMOTRIGINE  
TABLETS USP**

**200 mg**

**Rx Only**

**60 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

M.L. 321

Lot :

Exp.:

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Goa 403 511, India

Marketed by:

 **UNICHEM**  
PHARMACEUTICALS (USA), INC.

Rochelle Park, NJ 07662.

13002098  
R-02-07/2011

29300114164

(b) (4)

Each scored tablet contains  
200 mg of lamotrigine USP.

See package insert for  
Dosage and Administration.

Store at 20°-25°C (68°-77°F)  
[See USP Controlled Room  
Temperature] in a dry place.

Dispense in a tight,  
light-resistant container as  
defined in the USP.

**CAUTION :**  
Verify Product Dispensed.



13002697  
R-02-07/2011

NDC 29300-114-05

M.L. 321

# LAMOTRIGINE TABLETS USP

Lot :

Exp.:

**200 mg**

**Rx Only**

**500 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

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Manufactured by:  
**UNICHEM LABORATORIES LTD.**  
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Goa 403 511, India

Marketed by:



**UNICHEM**  
PHARMACEUTICALS (USA), INC.

Rochelle Park, NJ 07662.

(b) (4)

Each scored tablet contains  
**200 mg of lamotrigine USP.**  
See package insert for  
Dosage and Administration.  
**Store at 20°-25°C (68°-77°F)**  
**[See USP Controlled Room  
Temperature] in a dry place.**  
Dispense in a tight,  
light-resistant container  
as defined in the USP.  
**CAUTION :**  
Verify Product Dispensed.



13002698  
R-02-07/2011

NDC 29300-114-10

# LAMOTRIGINE TABLETS USP

**200 mg**

**Rx Only**  
**1000 Tablets**

**ATTENTION PHARMACIST :**  
Each patient is required to receive the  
accompanying Medication Guide

**UNICHEM**

M.L. 321

Lot :

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PHARMACEUTICALS (USA), INC.

Rochelle Park, NJ 07662.

13002701 Lamotrigine Tablets USP (Med. Guide) Open size: 280 x 480 mm Folding size: 36 x 40 mm (40 gsm Bible) Date: 12.07.2011 (Front) V-10



**MEDICATION GUIDE  
LAMOTRIGINE TABLETS USP**

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?**

**1. Lamotrigine tablets may cause a serious skin rash that may cause you to be hospitalized or to stop lamotrigine tablets; 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 lamotrigine tablets, within the first 2 to 8 weeks of treatment. But it can happen in people who have taken lamotrigine tablets 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 lamotrigine tablets.

The risk of getting a rash is higher if you:

- take lamotrigine tablets while taking valproate (valproic acid or divalproex sodium)
- take a higher starting dose of lamotrigine tablets than your healthcare provider prescribed
- increase your dose of lamotrigine tablets faster than prescribed.

Lamotrigine tablets 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 lamotrigine tablets.

**2. 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:

- 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 tablets without first talking to a healthcare provider.**

- Stopping lamotrigine 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?**

- 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.

**3. 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:

- Headache
- Fever
- Nausea
- Vomiting
- Stiff neck
- Rash
- Unusual sensitivity to light
- Muscle pains
- Chills
- Confusion
- 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?"

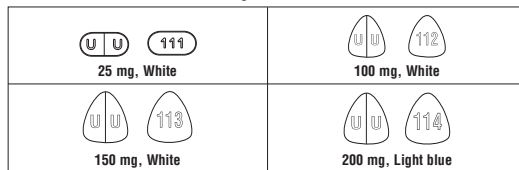
**4. Patients prescribed lamotrigine tablets have sometimes been given the wrong medicine because many medicines have names similar to lamotrigine tablets, so always check that you receive lamotrigine tablets.**

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

- 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 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 USP



**MEDICATION GUIDE  
LAMOTRIGINE TABLETS USP**

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- hives
- fever
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- 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

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- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
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- Fever
- Nausea
- Vomiting
- Stiff neck
- Rash
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- Muscle pains
- Chills
- Confusion
- Drowsiness

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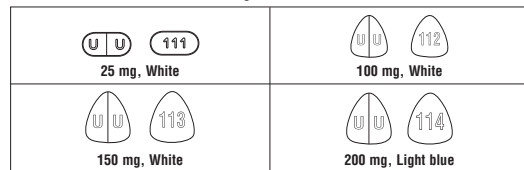
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- Make sure you can read it clearly.
- Talk to your pharmacist to check that you are given the correct medicine.
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These pictures show the distinct wording, colors, and shapes of the tablets that help 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 USP



13002701 Lamotrigine Tablets USP (Med. Guide) Open size: 280 x 480 mm Folding size: 36 x 40 mm (40 gsm Bible) Date: 12.07.2011 (Back) V-10

#### What is Lamotrigine tablet?

Lamotrigine tablet is a prescription medicine used:

- 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.
- alone when changing from other medicines used to treat partial seizures in people 16 years or older.
- 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 lamotrigine tablets are 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 lamotrigine tablets are safe or effective when used alone as the first treatment of seizures in adults.

#### 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.
- 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 break through bleeding. Stopping or starting these medicines may cause side effects (such as dizziness, lack of coordination, or double vision) or lessen how well lamotrigine tablets work.
- are pregnant or plan to become pregnant. It is not known if lamotrigine tablets 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 breast-feeding. Lamotrigine can pass into your breast milk. You and your healthcare provider should decide if you should take lamotrigine tablets or breast-feed. Breast-feeding while taking lamotrigine tablets 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 lamotrigine tablets with certain other medicines 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 get 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.**
- 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, 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 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
- 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 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). [See USP Controlled Room Temperature]
- 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.

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.

#### What are the ingredients in Lamotrigine tablets?

Active ingredient: Lamotrigine USP.

Inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycolate. In addition, the 200 mg tablets contain FD&C Blue No. 2 Lake.

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

Manufactured by:  
**UNICHEM LABORATORIES LTD.**  
Pile ne Ind. Estate, Pilerne, Bardez, Goa 403 511, India

Marketed by:



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#### What is Lamotrigine tablet?

Lamotrigine tablet is a prescription medicine used:

- 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.
- alone when changing from other medicines used to treat partial seizures in people 16 years or older.
- 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 lamotrigine tablets are 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 lamotrigine tablets are safe or effective when used alone as the first treatment of seizures in adults.

#### 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.
- 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 break through bleeding. Stopping or starting these medicines may cause side effects (such as dizziness, lack of coordination, or double vision) or lessen how well lamotrigine tablets work.
- are pregnant or plan to become pregnant. It is not known if lamotrigine tablets 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 breast-feeding. Lamotrigine can pass into your breast milk. You and your healthcare provider should decide if you should take lamotrigine tablets or breast-feed. Breast-feeding while taking lamotrigine tablets 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 lamotrigine tablets with certain other medicines 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 get 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.**
- 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, 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 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
- 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 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). [See USP Controlled Room Temperature]
- 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.

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.

#### What are the ingredients in Lamotrigine tablets?

Active ingredient: Lamotrigine USP.

Inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycolate. In addition, the 200 mg tablets contain FD&C Blue No. 2 Lake.

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

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