Lamotrigine Extended-Release Tablets

**USES**

Lamotrigine Extended-Release Tablets are used to treat epilepsy in adults and adolescents 12 years of age and older. Lamotrigine is also used to maintain improvement in symptoms of primary generalized tonic-clonic seizures and partial onset seizures in adults and children 12 years of age and older and primary generalized tonic-clonic seizures, partial onset seizures, and symptomatic idiopathic generalized epilepsy in children 12 months to 11 years of age.

**CONTRAINDICATIONS**

Lamotrigine Extended-Release Tablets are contraindicated in patients who are hypersensitive to lamotrigine or any of the excipients in the tablets.

**WARNINGS**

The risk of serious skin reactions (e.g., Stevens-Johnson syndrome and toxic epidermal necrolysis), including fatal outcomes, is increased in patients who are already sensitive to carbamazepine, phenytoin, valproic acid, or oxcarbazepine. Lamotrigine should be avoided in patients with a history of a serious skin reaction to any of these drugs. If lamotrigine is initiated in patients already taking one of these antiepileptic drugs (AEDs), careful observation is warranted.

**PRECAUTIONS**

1. Lamotrigine should be used with caution in patients with a history of suicidal behavior or ideation. Clinical monitoring is essential and should include close follow-up in the weeks following initiation of lamotrigine, especially if the dose is increased rapidly. If worsening or emergence of suicidality is noted, lamotrigine should be discontinued and appropriate medical intervention should be considered. If necessary, other treatments may be considered.

2. Lamotrigine should be used with caution in patients with a history of a serious skin reaction, such as Stevens-Johnson syndrome, to any drug. If lamotrigine is initiated in patients already taking one of these drugs, careful observation is warranted.

**ADVERSE REACTIONS**

The most common adverse reactions (occurring in at least 1/100 patients) include rash, hives, nausea, vomiting, diarrhea, stomatitis, dysgeusia, and neutropenia. Other adverse reactions include rash, gastrointestinal symptoms, and hematological abnormalities. Some patients may experience a rash that worsens over time and may become lifethreatening. Lamotrigine should be discontinued if a rash occurs.

**DOSAGE AND ADMINISTRATION**

Lamotrigine Extended-Release Tablets are available in the following strengths: 100 mg, 200 mg, 250 mg, and 300 mg. The recommended initial dosage for adults and adolescents 12 years of age and older is 100 mg once daily. For children 12 months to 11 years of age, the recommended initial dosage is 100 mg once daily. The dosage may be increased gradually, every 2 to 4 weeks, up to a maximum of 300 mg once daily. The recommended dosage for maintenance treatment is 100 mg to 300 mg once daily.

**NURSING MATERNAL CONSIDERATIONS**

There have been reports of fetal deaths and abnormal development in pregnant women whose epilepsy was inadequately controlled. Lamotrigine should be used during pregnancy only if the potential benefit justifies the risk to the mother. Lamotrigine should be avoided during breastfeeding.

**DRUG INTERACTIONS**

Lamotrigine is not generally administered in combination with other drugs. However, if a decision is made to combine lamotrigine with other antiepileptic drugs, the potential for drug interactions should be considered. The effects of lamotrigine on the pharmacokinetics of other drugs and the effects of other drugs on lamotrigine should be considered.

**HOW SUPPLIED**

Lamotrigine Extended-Release Tablets are available in bottles of 90 tablets, each containing 100 mg, 200 mg, 250 mg, or 300 mg of lamotrigine.

In the accompanying Medication Guide, depictions of the lamotrigine extended-release tablets can be found. Each lamotrigine extended-release tablet is debossed with "563" on one side and "Par" on the other.
Lamotrigine extended-release tablets may cause a serious skin rash that may be life-threatening. Call your doctor right away if you have any of the following:

- a skin rash
- hives
- swelling of the face, lips, tongue, or throat
- a skin rash or hives that spread or get worse
- dizziness

If you have these symptoms, stop taking lamotrigine extended-release tablets and call your doctor right away.

Lamotrigine extended-release tablets can also cause other types of allergic reactions or serious problems that may affect organs and other parts of your body like the liver or blood cells. You may or may not have rashes with these types of reactions.

Call your healthcare provider right away if you have any of the following:

- a skin rash
- hives
- swelling of the face, lips, tongue, or throat
- dizziness
- unusual tiredness or weakness
- muscle pain
- impaired vision

These symptoms may be the first signs of a serious allergic reaction. A healthcare provider should examine you to decide if you should continue taking lamotrigine extended-release tablets.

Lamotrigine extended-release tablets can cause skin problems that may affect organs and other parts of your body like the liver or blood cells. You may or may not have rashes with these types of reactions.

Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- nausea
- vomiting
- diarrhea
- weight loss
- stomach pain
- discoloration of your skin
- hives
- rash

These symptoms may be the first signs of a serious allergic reaction. A healthcare provider should examine you to decide if you should continue taking lamotrigine extended-release tablets.

Lamotrigine extended-release tablets may cause suicidal thoughts or actions in a very small number of people. Call your healthcare provider right away if you have any of these problems, especially if they are new, worse, or worry you:

- feeling depressed or more sad than usual
- feeling restless, irritable, or亢	onous
- having trouble sleeping
- losing interest in activities
- feeling like you might hurt yourself or get into a bad accident
- any other change in mood or behavior
- thoughts about suicide
- thoughts of harming yourself or of dying

Tell your healthcare provider about any of these problems, especially if they are new, worse, or worry you:

- unusual bleeding or bruising
- nosebleeds
- unusual infections

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