

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use lamotrigine safely and effectively. See full prescribing information for lamotrigine.

Lamotrigine Tablets (Chewable, Dispersible)
Initial U.S. Approval: 1994

WARNING: SERIOUS SKIN RASHES

See full prescribing information for complete boxed warning.

Cases of life-threatening serious rashes, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS), associated with lamotrigine. The rate of serious rash is greater in pediatric patients than in adults. Additional factors that may increase the risk of rash include (5.1):

- concomitant with valproate
- exceeding recommended initial dose of lamotrigine
- exceeding recommended dose escalation of lamotrigine

Benign rashes are also caused by lamotrigine; however, it is not possible to predict which rashes will prove to be serious or life-threatening. Lamotrigine should be discontinued at the first sign of rash, unless the rash is clearly not drug-related. (5.1)

RECENT MAJOR CHANGES

Warnings and Precautions, Aseptic Meningitis (5.7) Month Year

INDICATIONS AND USAGE

Lamotrigine is an antiepileptic drug (AED) indicated for:

Epilepsy—adjunctive therapy in patients > 2 years of age: (1.1)

- partial seizures.
- primary generalized tonic-clonic seizures.
- generalized seizures of Lennox-Gastaut syndrome.

Epilepsy—monotherapy in patients > 16 years of age:
Conversion to monotherapy in patients with partial seizures who are receiving treatment with carbamazepine, phenobarbital, phenytoin, primidone, or valproate as the single AED (1.1).

Bipolar Disorder in patients > 18 years of age:
Maintenance treatment of Bipolar I Disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy (1.2)

DOSAGE AND ADMINISTRATION

Dosing is based on concomitant medications, indication, and patient age. (2.2, 2.4)

- To avoid an increased risk of rash, the recommended initial dose and subsequent dose escalations should not be exceeded. (2.1)

- Do not restart lamotrigine in patients who discontinued due to rash unless the potential benefits clearly outweigh the risks. (2.1)

- Adjustments to maintenance doses will in most cases be required in patients starting or stopping estrogen-containing oral contraceptives. (2.1, 5.9)

- Lamotrigine should be discontinued over a period of at least 2 weeks (approximately 50% reduction per week). (2.1, 5.10)

Epilepsy

- Adjunctive therapy See Table 1 for patients >12 years of age and Tables 2 and 3 for patients 2 to 12 years. (2.2)

- Conversion to monotherapy See Table 4. (2.3)

Bipolar Disorder: See Tables 5 and 6. (2.4)

DOSAGE FORMS AND STRENGTHS

Tablets: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg (3.1, 16)

Tablets (Chewable, Dispersible): 5 mg, and 25 mg. (3.2, 16)

CONTRAINDICATIONS

Hypersensitivity to the drug or its ingredients. (Boxed Warning, 4)

WARNINGS AND PRECAUTIONS

- Life-threatening serious rash and/or rash-related death may result. (Boxed Warning, 5.1)
- Hypersensitivity reaction may be fatal or life-threatening. Early signs of hypersensitivity

(e.g., fever, lymphadenopathy) may present without rash; if signs present, patient should be evaluated immediately. Lamotrigine should be discontinued if alternate etiology for hypersensitivity signs is not found. (5.2)

- Acute multiorgan failure has resulted (some cases fatal). (5.3)
- Blood dyscrasias (e.g., neutropenia, thrombocytopenia, pancytopenia), may result either with or without an associated hypersensitivity syndrome. (5.4)
- Suicidal behavior and ideation. (5.5)
- Clinical worsening, emergence of new symptoms, and suicidal ideation/behaviors may be associated with treatment of bipolar disorder. Patients should be closely monitored, particularly early in treatment or during dosage changes. (5.6)
- Aseptic meningitis reported in pediatric and adult patients. (5.7)
- Medication errors involving lamotrigine have occurred. In particular the names lamotrigine can be confused with names of other commonly used medications. Medication errors may also occur between the different formulations of lamotrigine. (3.4, 5.8, 16, 17.9)

ADVERSE REACTIONS

- Most common adverse reactions (incidence > 10%) in adult epilepsy clinical studies were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, and rash. Additional adverse reactions (incidence > 10%) reported in children in epilepsy clinical studies included vomiting, infection, fever, accidental injury, pharyngitis, abdominal pain, and tremor. (6.1)
- Most common adverse reactions (incidence > 5%) in adult bipolar clinical studies were nausea, insomnia, somnolence, back pain, fatigue, rash, rhinitis, abdominal pain, and xerostomia. (6.1)

USE IN SPECIFIC POPULATIONS

- Hepatic impairment: Dosage adjustments required. (2.1)
- Patients can enroll themselves in the North American Antiepileptic Drug Pregnancy Registry (1-888-233-2334). (8.1)
- Efficacy of lamotrigine, used as adjunctive therapy for partial seizures, was not demonstrated in a small randomized, double-blind, placebo-controlled study in very young pediatric patients (1 to 24 months). (8.4)

DRUG INTERACTIONS

- Valproate increases lamotrigine concentrations more than 2-fold. (7, 12.3)
- Carbamazepine, phenytoin, phenobarbital, and primidone decrease lamotrigine concentrations by approximately 40%. (7, 12.3)
- Oral estrogen-containing contraceptives and rifampin also decrease lamotrigine concentrations by approximately 50%. (7, 12.3)

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WARNINGS AND PRECAUTIONS

- 5.1 Serious Skin Rashes (see BOXED WARNING)
- 5.2 Hypersensitivity Reactions
- 5.3 Acute Multiorgan Failure
- 5.4 Blood Dyscrasias
- 5.5 Suicidal Behavior and Ideation
- 5.6 Use in Patients with Bipolar Disorder
- 5.7 Aseptic Meningitis
- 5.8 Potential Medication Errors
- 5.9 Concomitant Use with Oral Contraceptives
- 5.10 Withdrawal Seizures
- 5.11 Status Epilepticus
- 5.12 Sudden Unexplained Death in Epilepsy (SUDEP)
- 5.13 Addition of Lamotrigine to a Multidrug Regimen That Includes Valproate
- 5.14 Binding in the Eye and Other Melanin-Containing Tissues
- 5.15 Laboratory Tests

ADVERSE REACTIONS

- 6.1 Clinical Trials
- 6.2 Other Adverse Reactions Observed in All Clinical Trials
- 6.3 Postmarketing Experience

DRUG INTERACTIONS

USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Labor and Delivery
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Patients with Hepatic Impairment
- 8.7 Patients with Renal Impairment

OVERDOSAGE

- 10.1 Human Overdose Experience
- 10.2 Management of Overdose

DESCRIPTION

CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

CLINICAL STUDIES

- 14.1 Epilepsy
- 14.2 Bipolar Disorder

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

- 17.1 Rash
- 17.2 Suicidal Thinking and Behavior
- 17.3 Worsening of Seizures
- 17.4 CNS Adverse Effects
- 17.5 Blood Dyscrasias and/or Acute Multiorgan Failure
- 17.6 Pregnancy
- 17.7 Oral Contraceptive Use
- 17.8 Discontinuing Lamotrigine
- 17.9 Aseptic Meningitis
- 17.10 Potential Medication Errors
- 17.11 Phenylketonurics

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: SERIOUS SKIN RASHES

Lamotrigine can cause serious rashes requiring hospitalization and discontinuation of treatment. The incidence of these rashes, which have included Stevens-Johnson syndrome, is approximately 0.8% (8 per 1,000) in pediatric patients (2 to 16 years of age) and 0.5% (5 per 1,000) in adult patients (17 years of age and older). The rate of serious rash is greater in pediatric patients than in adults. Additional factors that may increase the risk of rash include (5.1):

- concomitant with valproate
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Benign rashes are also caused by lamotrigine; however, it is not possible to predict which rashes will prove to be serious or life-threatening. Lamotrigine should be discontinued at the first sign of rash, unless the rash is clearly not drug-related. (5.1)

RECENT MAJOR CHANGES

Warnings and Precautions, Aseptic Meningitis (5.7) Month Year

INDICATIONS AND USAGE

