



LAMOTRIGINE tablets USP, for oral use



08110166

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use LAMOTRIGINE TABLETS safely and effectively. See full prescribing information for LAMOTRIGINE TABLETS.

LAMOTRIGINE TABLETS, for oral use

U.S. Approved: 1994

WARNING: SERIOUS SKIN RASHES

- **Case of life-threatening serious rash, including Stevens-Johnson syndrome and toxic epidermal necrolysis, and/or rash-related death have been caused by lamotrigine. The rate of serious rash is greater in pediatric patients than in adults. Additional factors that may increase the risk of rash include:**
 - **concomitant use with valproate,**
 - **exceeding recommended dose escalation for lamotrigine,**
 - **presence of the HLA-B*1502 allele. (5.1)**
- **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

- Boxed Warning and Administration (2.1, 2.2, 2.4)
- Warnings and Precautions, Serious Skin Reactions, Concomitant Use with Estrogen-Containing Products, Including Oral Contraceptives (5.3)
- Sudden Unexplained Death in Epilepsy (5.12) - removal, 4/2025

INDICATIONS AND USAGE

Lamotrigine is indicated for:

- **Epilepsy—adjunctive therapy in patients aged 2 years and older,**

- **primary generalized tonic-clonic (PGTC) seizures,**

- **partial-onset seizures,**

- **primary generalized tonic-clonic (PGTC) seizures,**

- **generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

- **primary generalized tonic-clonic (PGTC) seizures.**

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- **Life-threatening serious rash and/or rash-related death.**

- **Discontinue at the first sign of rash, unless the rash is clearly not drug related. (Boxed Warning, 5.1)**

- **Hemophagocytic lymphohistiocytosis.**

- **Consider this diagnosis and evaluate patients immediately if they develop signs or symptoms of systemic inflammation. Discontinue lamotrigine if an alternative etiology is not established. (5.2)**

- **Fatal or life-threatening hypersensitivity reactions.**

- **Multiorgan hypersensitivity reactions, also known as drug reaction with eosinophilia and systemic symptoms, may be fatal or life threatening. Early signs may include rash, fever, and lymphadenopathy. These reactions may be associated with other organ involvement, such as hepatitis, hepatic failure, blood dyscrasias, or acute multiorgan failure. Lamotrigine should be discontinued if alternate etiology for this reaction is not found immediately. (5.3)**

- **Cardiac rhythm and conduction abnormalities.**

- **Based on *in vitro* findings, lamotrigine could cause serious arrhythmias and/or death in patients with certain underlying cardiac disorders or arrhythmias. Any expected or observed benefit of lamotrigine in an individual patient with clinically important structural or functional heart disease must be carefully weighed against the risk for serious arrhythmias and/or death for that patient. (5.4)**

- **Medication errors due to product name confusion.**

- **Medication errors due to product name confusion. Strongly advise patients to visually inspect the received drug or device. (5.8, 16.1)**

ADVERSE REACTIONS

Epilepsy: Most common adverse reactions (incidence >10%):

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

- **headache, dizziness, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.**

