HOW TO WRITE

Lamotrigine Tablets, USP

Simplify Treatment from the Start

Generic Lamotrigine Starter Kits

Now on Medicaid

Initiate Treatment in a Structured Way with Lamotrigine STARTER KITS

1 **E-Prescribe Lamotrigine Starter Kit (Orange, Blue, or Green)**

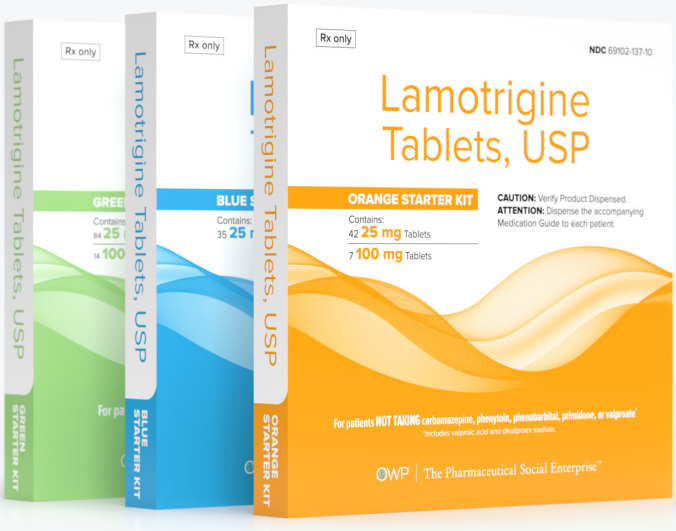
A

In your EMR system, go to the full list of lamotrigine medications

B

- Look for "Kit, Starter Kit or Dose Pack"
- Then for "Orange, Blue or Green"
- Select appropriate Kit by clicking on it

2 **Save the selected Lamotrigine Starter Kit as a "favorite" for quick access in the future**



Orange Starter Kit:

Total 49 Tablets (42 X 25mg) (7 X 100mg) NDC 69102-137-10

Blue Starter Kit:

Total 35 Tablets (35 X 25mg) NDC 69102-639-09

Green Starter Kit:

Total 98 Tablets (84 X 25mg) (14 X 100mg) NDC 69102-359-11

Pharmacists: Please use the NDC numbers listed above to place orders.

Our representatives are here for you every step of the way, including help for your patients if needed at the pharmacy.

For questions or more information please contact: info@owppharma.com or 1-800-273-6729

OWP® | The Pharmaceutical Social Enterprise®

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS SKIN RASHES

Cases of life-threatening serious rashes, 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:

- coadministration 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.

Please refer to the full Prescribing Information for Lamotrigine Tablets, including Medication Guide at www.lamotriginestarterkits.com.

Lamotrigine Tablets, USP are indicated for:

Epilepsy—adjunctive therapy in patients aged 2 years and older:

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

Epilepsy—monotherapy in patients aged 16 years and older: Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug.

Bipolar disorder: 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.

LIMITATIONS OF USE

Treatment of acute manic or mixed episodes is not recommended. Effectiveness of Lamotrigine in the acute treatment of mood episodes has not been established.

CONTRAINDICATIONS

Lamotrigine is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

WARNINGS & PRECAUTIONS

- Cases of life-threatening serious rashes, including Stevens-Johnson syndrome, 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. Refer to **Lamotrigine – BOXED WARNING**.
- Lamotrigine should not be abruptly discontinued. In patients with epilepsy there is a possibility of increasing seizure frequency. Unless safety concerns require a more rapid withdrawal, the dose of Lamotrigine should be tapered over a period of at least 2 weeks. Refer to Lamotrigine – DOSAGE AND ADMINISTRATION.
- Hemophagocytic lymphohistiocytosis (HLH) has occurred in adult and pediatric patients taking Lamotrigine. HLH is a life-threatening syndrome of pathologic immune activation characterized by clinical signs and symptoms of extreme systemic fibrosis. It is associated with high mortality rates if not recognized early and treated. HLH has presented with systemic inflammation (fever, rash, hepatosplenomegaly, and organ system dysfunction) and blood dyscrasias. Symptoms have been reported to occur within 8 to 24 days following the initiation of treatment. Patients who develop early manifestations of pathologic immune activation should be evaluated immediately, and a diagnosis of HLH should be considered.
- Multiorgan hypersensitivity reactions, also known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have occurred with Lamotrigine. Some have been fatal or life threatening. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy in association with other organ system involvement, such as hepatitis, nephritis, hematologic abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. This disorder is variable in its expression, and other organ systems not noted here may be involved. Fatalities associated with acute multiorgan failure and various degrees of hepatic failure have been reported. Prior to initiation of treatment with Lamotrigine, the patient should be instructed that a rash or other signs or symptoms of hypersensitivity (e.g., fever, lymphadenopathy) may herald a serious medical event and that the patient should report any such occurrence to a healthcare provider immediately.
- In vitro testing showed that Lamotrigine exhibits Class IB antiarrhythmic activity at therapeutically relevant concentrations. Based on these in vitro findings, Lamotrigine could slow ventricular conduction (widen QRS) and induce proarrhythmia, which can lead to sudden death, in patients with clinically important structural or functional heart disease (i.e., patients with heart failure, valvular heart disease, congenital heart disease, conduction system disease, ventricular arrhythmias, cardiac channelopathies [e.g., Brugada syndrome], clinically important ischemic heart disease, or multiple risk factors for coronary artery disease). 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 risks for serious arrythmias and/or death for that patient. Concomitant use of other sodium channel blockers may further increase the risk of proarrhythmia.
- There have been reports of blood dyscrasias that may or may not be associated with multiorgan hypersensitivity (also known as DRESS). These have included neutropenia, leukopenia, anemia, thrombocytopenia, pancytopenia, and, rarely, aplastic anemia and pure red cell aplasia.
- Antiepileptic drugs (AEDs), including Lamotrigine, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Anyone prescribing Lamotrigine must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment with Lamotrigine, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated. Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.
- Therapy with Lamotrigine increases the risk of developing aseptic meningitis. Because of the potential for serious outcomes of untreated meningitis due to other causes, patients should also be evaluated for other causes of meningitis and treated as appropriate.
- Medication errors involving Lamotrigine have occurred. In particular, the name Lamotrigine or lamotrigine can be confused with the names of other commonly used medications. Medication errors may also occur between the different formulations of Lamotrigine.
- Some estrogen-containing oral contraceptives have been shown to decrease serum concentrations of lamotrigine. Dosage adjustments will be necessary in most patients who start or stop estrogen-containing oral contraceptives while taking Lamotrigine.
- Valid estimates of the incidence of treatment-emergent status epilepticus among patients treated with Lamotrigine are difficult to obtain because reporters participating in clinical trials did not all employ identical rules for identifying cases. At a minimum, 7 of 2,343 adult patients had episodes that could unequivocally be described as status epilepticus. In addition, a number of reports of variably defined episodes of seizure exacerbation (e.g., seizure clusters, seizure flurries) were made.
- During the premarketing development of Lamotrigine, 20 sudden and unexplained deaths were recorded among a cohort of 4,700 patients with epilepsy (5,747 patient-years of exposure).
- Because valproate reduces the clearance of lamotrigine, the dosage of Lamotrigine in the presence of valproate is less than half of that required in its absence.
- Because lamotrigine binds to melanin, it could accumulate in melanin-rich tissues over time. This raises the possibility that lamotrigine may cause toxicity in these tissues after extended use. Although there are no specific recommendations for periodic ophthalmological monitoring, prescribers should be aware of the possibility of long-term ophthalmologic effects.
- There have been reports of decreased lamotrigine concentrations during pregnancy and restoration of pre-partum concentrations after delivery. As with other AEDs, physiological changes during pregnancy may affect lamotrigine concentrations and/or therapeutic effect. Dosage adjustments may be necessary to maintain clinical response.
- Lamotrigine is present in milk from lactating women taking Lamotrigine. Caution should be exercised when Lamotrigine is administered to a nursing woman.
- Safety and efficacy of Lamotrigine used as adjunctive treatment for partial-onset seizures in very young pediatric patients (aged 1 to 24 months) has not been demonstrated.
- Safety and efficacy of Lamotrigine for the maintenance treatment of bipolar disorder in pediatric patients has not been demonstrated.
- Because lamotrigine is metabolized predominantly by glucuronic acid conjugation, drugs that are known to induce or inhibit glucuronidation may affect the apparent clearance of lamotrigine and doses of Lamotrigine may require adjustment based on clinical response.

DOSING GUIDELINES & CONSIDERATIONS

- Refer to the Lamotrigine - DOSAGE AND ADMINISTRATION section of the full prescribing information for recommended dosing guidelines for Lamotrigine.
- There are a number of significant drug interactions with Lamotrigine. Refer to the Lamotrigine - DRUG INTERACTIONS section of the full prescribing information.

ADVERSE REACTIONS

- See the ADVERSE REACTIONS section of the Lamotrigine full prescribing information for adverse reaction rates from clinical trials conducted under widely varying conditions.
- The most common adverse reactions (incidence ≥10%) in adults were dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash. Additional adverse reactions (incidence ≥10%) reported in children included vomiting, infection, fever, accidental injury, diarrhea, abdominal pain, and tremor.
- The most common adverse reactions (incidence >5%) in adults with bipolar disorder were nausea, insomnia, somnolence, back pain, fatigue, rash, rhinitis, abdominal pain, and xerostomia.
- To report SUSPECTED ADVERSE REACTIONS, contact OWP Pharmaceuticals Inc. at 1-800-273-6729 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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