

Lamotrine Tablets

Lamotrigine

COMPOSITION:

Lamotrine 2 mg chewable dispersible tablets: 2 mg lamotrigine.
Lamotrine 25 mg tablets: 25 mg lamotrigine.
Lamotrine 50 mg tablets: 50 mg lamotrigine.
Lamotrine 100 mg tablets: 100 mg lamotrigine.

PHARMACOLOGICAL PROPERTIES:

Lamotrigine is an anti-epileptic drug. It acts through blockage of voltage-sensitive sodium channels to stabilize the neuronal membranes. This results in inhibition of excitatory amino acids during epileptogenesis. Lamotrigine acts on neurons displaying epileptiform activity and has no effect on normal neuronal activity. Lamotrigine is rapidly and completely absorbed after oral intake. Oral bioavailability is 98%, protein binding is 55% and half-life is 24-25 hours.

INDICATIONS:

- **Add on therapy:** It is indicated as add on therapy in partial and generalized seizures and the seizures associated with Lennox-Gastaut syndrome in pediatric and adult patients.
- **Monotheapy:** It is indicated for conversion to monotherapy in adults with partial seizures who are receiving treatment with single EIAEDs (Enzyme Inducing Anti-Epileptic Drugs).

PRECAUTIONS & WARNINGS:

- It should be discontinued at first signs of rash, unless the rash is clearly not drug related.
 - It should not be used for simultaneous conversion from two or more AED (Anti-Epileptic Drugs).
 - It should not be used for conversion from non EIAEDs (as valproate).
- Lamotrigine can cause aseptic meningitis. Symptoms of meningitis may include headache, stiff neck, nausea, vomiting, rash, and sensitivity to light. In cases of meningitis, it is important to rapidly diagnose the underlying cause so that treatment can be promptly initiated. Patients should be advised to contact their healthcare professional immediately if they experience signs & symptoms of meningitis while taking lamotrigine. If meningitis is suspected, patients should be evaluated for other causes of meningitis and treated as indicated.
- Discontinuation of lamotrigine should be considered if no other clear causes of meningitis is identified.
- Antiepileptic drugs (AEDs) 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.

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. 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.

CONTRAINDICATION:

Hypersensitivity to lamotrigine.

SIDE EFFECTS:

- Headache, nausea, dizziness, insomnia, ataxia, diplopia, blurred vision and coordination abnormalities.
- Weight decrease, chest pain, dysmenorrhea and anxiety are infrequent side effects.

DOSAGE:

When Lamotrine is added to an AED regimen containing valproate in patients over 12 years:

Weeks 1 and 2	25 mg every other day	Weeks 3 and 4	25 mg every day
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Usual maintenance dose: 100 - 400 mg/day (1 or 2 divided doses). To achieve maintenance, dose may be increased by 25 - 50 mg/day every 1 to 2 weeks.

Usual maintenance dose in patients adding Lamotrine to valproate alone ranges from 100 to 200 mg/day.

Lamotrine added to EIAEDs (without VPA) in patients over 12 years of age:

Weeks 1 and 2	50 mg / day	Weeks 3 and 4	100 mg / day in 2 divided doses
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Usual maintenance dose is 300 - 500 mg/day (in 2 divided doses).

To achieve maintenance doses may be increased by 100 mg/day every 1-2 weeks.

The recommended maintenance dose of Lamotrine as monotherapy is 500 mg/day given in 2 divided doses.

Dose for children with Lennox-Gastaut syndrome from 100-300 mg/day.

Lamotrine added to AED regimen containing VPA in patients from 2 to 12 years of age:

Weeks 1 and 2	0.15 mg/kg/day (In one or 2 divided doses)	Weeks 3 and 4	0.3 mg/kg/day (in one or 2 divided doses)
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Lamotrine added to EIAEDs (without VPA) in patients from 2 to 12 years of age:

Weeks 1 and 2	0.6 mg/kg/day (In 2 divided doses)	Weeks 3 and 4	0.2 mg/kg/day (In 2 divided doses)
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Usual maintenance dose is 5-15 mg/kg day (max 400 mg /day in 2 divided doses). To achieve maintenance, the subsequent doses should be increased every 1 to 2 weeks as follows: Calculate 1.2 mg/kg/day, add this amount to previously administered daily dose.

PACKAGE AND STORAGE:

Lamotrine 2mg chewable dispersible tablets: 30 Tablets / Pack.
Lamotrine 25 mg: 30 Tablets / Pack.
Lamotrine 50 mg: 30 Tablets / Pack.
Lamotrine 100 mg: 30 Tablets / Pack.
Store at temperature not exceeding 30° C.

Keep All Medicines Out of Reach of Children