Abridged Prescribing Information:

Active Ingredient: LAMEZ 25 / 50/ 100 mg dispersible tablets contain lamotrigine 25/50/100 mg. LAMEZ OD 25 / 50/ 100 / 150/ 200 mg modified release tablets contain lamotrigine 25/50/100 /150 / 200 mg

Indication: (i) Epilepsy: (a) Adults and adolescents aged 13 years and above- Adjunctive or monotherapy treatment of partial seizures and generalized seizures, including tonic-clonic seizures, seizures associated with Lennox-Gastaut syndrome. Lamotrigine tablet is given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox-Gastaut syndrome. (b) Children and adolescents aged 2 to 12 years - Adjunctive treatment of partial seizures and generalized seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome, monotherapy of typical absence seizures. (ii) Bipolar disorder: Adults aged 18 years and above - Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes. **Dosage & Administration:** (i) Epilepsy (a) Monotherapy: *Adults and children over 13 years of age*: 25 mg once a day for first 2 weeks, followed by 50 mg once a day for 2 weeks. Maintenance dose is 100 to 200 mg/day. *For children (2-12 years)*: 0.3 mg/kg/day for first 2 weeks, followed by 0.6 mg/kg/day for next 2 weeks. Maintenance dose is 1-15 mg/kg/day. (b) Adjunctive Therapy: Adults and children over 13 years of age: In those patients taking valproate, the initial lamotrigine dose is 25 mg every alternate day for 2 weeks, followed by 25 mg/day for 2 weeks. Maintenance dose is 100 to 200 mg/day. The initial lamotrigine dose in those patients not taking valproate is 50 mg once a day for 2 weeks, followed by 100 mg/day given in two divided doses for two weeks. Maintenance dose is 200 to 400 mg/day. In those patients taking other medications that do not significantly inhibit or induce lamotrigine glucuronidation, the initial lamotrigine dose is 25 mg / day for 2 weeks, then 50 mg/day for 2 weeks & maintenance dose is 100 to 200 mg/day. *For children (2-12 years)*: In patients taking valproate, the initial lamotrigine dose is 0.15 mg/kg /day for 2 weeks, followed by 0.3 mg/kg/day given once a day for 2 weeks. Maintenance dose is 1-5 mg/kg day, with a maximum of 200 mg/day. In those patients taking concomitant AEDs or other medicines that induce lamotrigine glucuronidation, the initial lamotrigine dose is 0.6 mg/kg /day for 2 weeks, followed by 1.2 mg/kg /day for two weeks. Maintenance dose is 5-15 mg/kg/day, with a maximum of 400 mg/day. In patients taking other medications that do not significantly inhibit or induce lamotrigine glucuronidation, the initial lamotrigine dose is 0.3 mg/kg/day given for 2 weeks, followed by 0.6 mg/kg/day for 2 weeks. Maintenance dose is 1 to 10 mg/kg/day, with a maximum of 200 mg/day. (ii) Bipolar I disorder: The target dose is 200 mg/day (100 mg/day in patients taking valproate, which decreases the apparent clearance of lamotrigine, and 400 mg/day in patients not taking valproate and taking either carbamazepine, phenytoin, phenobarbital, primidone, or rifampin, which increase the apparent clearance of lamotrigine. **Contraindications:** Known hypersensitivity to product components. **Warnings & Precautions:** Suicidal behavior and ideation, blood dyscrasias, aseptic meningitis, concomitant use with oral contraceptives, sudden unexplained death in epilepsy (SUDEP), serious skin rashes. Lamotrigine should ordinarily be discontinued at the first sign of rash. Lamotrigine should be withdrawn gradually to minimize the potential of increased seizure frequency. **Pregnancy & Lactation:** Pregnancy Category C. Potential benefit to the mother should be weighed against the potential risk to the infant when considering recommendations regarding nursing. **Interaction:** Valproate increases lamotrigine concentrations more than 2-fold. Carbamazepine, phenytoin, phenobarbital, and primidone decrease lamotrigine concentrations by approximately 40%. Oral estrogen-containing contraceptives and rifampin also decrease lamotrigine concentrations by approximately 50%. Since lamotrigine is metabolized predominately 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. **Adverse Reactions:** 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. **Overdose:** Overdose involving quantities up to 15 g has resulted in ataxia, nystagmus, increased seizures, decreased level of consciousness, coma, and intraventricular conduction delay. There are no specific antidotes for lamotrigine. Following a suspected overdose, hospitalization of the patient is advised. *(For details, please refer full prescribing information)*

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