LEMIC TABLETS

(Lamotrigine 25 mg)

COMPOSITION

Each tablet contains Lamotrigine 25 mg. Excipients are according to the approved formulation.

DESCRIPTION

Lamotrigine is an antiepileptic medicine of the phenyltriazine class. It is also used as maintenance therapy in bipolar I disorder in appropriate patients.

CLINICAL PHARMACOLOGY

Lamotrigine inhibits voltage-sensitive sodium channels and modulates release of excitatory neurotransmitters, including glutamate. It is absorbed orally and is metabolized mainly by glucuronidation. Its elimination is substantially affected by concomitant medicines such as valproate and enzyme-inducing antiepileptics.

INDICATIONS

Epilepsy: adjunctive treatment of focal (partial-onset) seizures, primary generalized tonic-clonic seizures and generalized seizures associated with Lennox-Gastaut syndrome in patients aged 2 years and above. Conversion to monotherapy in eligible patients aged 16 years and above with partial-onset seizures, under specialist supervision. Bipolar I disorder: maintenance treatment in adults to delay recurrence of mood episodes after standard treatment of acute episodes. Not established for acute mania or acute mood episodes.

DOSAGE AND ADMINISTRATION

Important: Treatment must be initiated and adjusted by a physician. Dose depends on indication, age, other medicines and liver/kidney function. Start at a low dose and increase gradually; never exceed the recommended initial dose or escalation schedule because serious rash may occur. Tablets should be swallowed with water, with or without food.

ADULT TITRATION EXAMPLE

For bipolar I maintenance in adults not receiving valproate or enzyme-inducing medicines: weeks 1-2, 25 mg once daily; weeks 3-4, 50 mg daily; week 5, 100 mg daily; week 6 onwards, usual target 200 mg daily, as prescribed. With valproate: the initial dose is commonly 25 mg every other day for weeks 1-2. With certain enzyme inducers: different, higher-dose schedules apply. These regimens are not interchangeable. Epilepsy regimens, especially in children, require weight- and co-medication-specific titration.

MISSED DOSES / DISCONTINUATION

If several doses are missed, contact the prescriber before restarting; a new titration may be necessary. Do not double a missed dose. Do not stop abruptly; withdrawal is generally gradual over at least 2 weeks unless rapid discontinuation is needed for safety.

CONTRAINDICATIONS

Known hypersensitivity to lamotrigine or any ingredient of the formulation.

SERIOUS SKIN RASH WARNING

Lamotrigine can cause life-threatening skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis. The risk is higher in children and with valproate, high starting doses, rapid dose increases or certain genetic susceptibility. Stop lamotrigine at the first sign of rash and obtain urgent medical assessment unless the rash is clearly unrelated to the medicine. Seek emergency care for blistering, peeling, mouth sores, fever, facial swelling or eye involvement. Do not restart after a lamotrigine-related rash unless a specialist determines that the benefit clearly outweighs the risk.

WARNINGS AND PRECAUTIONS

Severe multiorgan hypersensitivity (DRESS), hemophagocytic lymphohistiocytosis (HLH), aseptic meningitis, blood disorders and liver injury have been reported. Fever, swollen glands, unusual bruising, persistent headache or neck stiffness require prompt evaluation even without rash. Monitor for depression, suicidal thoughts or significant behavior changes. Use caution with underlying cardiac conduction disorders or structural heart disease. Assess liver and kidney impairment before dose adjustment.

DRUG INTERACTIONS

Valproate reduces lamotrigine clearance and increases rash risk. Carbamazepine, phenytoin, phenobarbital and primidone can increase clearance. Estrogen-containing contraceptives can lower lamotrigine levels; starting or stopping them may require dose changes. Rifampicin and some antiretrovirals may alter concentrations. Tell the prescriber about every medicine and contraceptive used.

PREGNANCY

Use during pregnancy only after individual evaluation of benefits and risks. Uncontrolled seizures may harm mother and fetus. Lamotrigine clearance may rise during pregnancy and fall rapidly after delivery; clinical review and blood-level monitoring may be needed. Do not discontinue treatment without medical advice. Discuss appropriate folate supplementation with the prescriber.

LACTATION

Lamotrigine enters breast milk. If breastfeeding, monitor the infant for rash, unusual sleepiness, poor feeding, apnea or poor weight gain; seek medical assessment if these occur. A clinician should assess benefits and risks.

PEDIATRIC AND GERIATRIC USE

Paediatric epilepsy treatment requires age-, weight- and medicine-specific dosing. Safety and efficacy for bipolar maintenance in children are not established. In older adults, use clinical judgment and consider organ function and concurrent medicines.

ADVERSE REACTIONS

Common effects include dizziness, headache, double or blurred vision, nausea, vomiting, ataxia, sleepiness, insomnia, tremor and rash. Other reported effects include fatigue, incoordination and gastrointestinal upset. Serious reactions include severe rash, hypersensitivity with organ involvement, blood disorders, aseptic meningitis and suicidal ideation. Seek urgent care for severe symptoms.

EFFECTS ON DRIVING

Dizziness, visual disturbance and impaired coordination may occur. Do not drive or operate machinery until individual response is known.

OVERDOSAGE

Overdose may cause nystagmus, ataxia, impaired consciousness, seizures or cardiac conduction abnormalities. Seek emergency medical care immediately. Management is supportive and includes clinical monitoring; there is no specific antidote.

STORAGE CONDITIONS

Store according to the approved pack label, protected from moisture and excessive heat. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Lemic Tablets 25 mg: 3 x 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.