Lamicet™

Lamotrigine USP

COMPOSITION

Lamicet™ 50 tablet: Each tablet contains Lamotrigine USP 50 mg.

PHARMACOLOGY

Lamotrigine controls epileptic seizures by inhibiting voltage-sensitive sodium channels, thereby stabilizes neuronal membranes and consequently inhibits presynaptic excitatory neurotransmitter (e.g., glutamate and aspartate) release.

INDICATIONS AND USAGE

Lamotrigine is an antiepileptic drug (AED) 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
Bipolar disorder in patients aged 18 years and older

DOSAGE & ADMINISTRATION

1. Monotherapy of seizures (adult and child over 12 years):
Initially 25 mg once daily for 14 days, then 50 mg once daily for further 14 days, then increased by maximum 50 mg/day every 7–14 days; usual maintenance dose 225–375 mg/day in 1–2 divided doses.
2. a. Adjunctive therapy of seizures with Valproate
Adult and child over 12 years:
Initially 25 mg on alternate days for 14 days, then 25 mg once daily for further 14 days, thereafter increased by maximum 25–50 mg/day every 7–14 days; usual maintenance, 100–200 mg/day in 1–2 divided doses.
Child 2–12 years:
Initially 150 micrograms/kg/day in 1-2 divided doses for 14 days (those weighing under 13 kg may receive 2 mg on alternate days for first 14 days), then 300 micrograms/kg/day in 1-2 divided doses for further 14 days, thereafter increased by maximum 300 micrograms/kg/day every 7–14 days; usual maintenance 1–3 mg/kg/day in 1–2 divided doses.
2. b. Adjunctive therapy of seizures (with enzyme inducing drugs e.g., Carbamazepine, Phenytoin, Phenobarbital, or Primidone) without Valproate
Adult and child over 12 years:
Initially 50 mg once daily for 14 days, then 50 mg twice daily for further 14 days, thereafter increased by maximum 100 mg/day in every 7–14 days; usual maintenance 300–500 mg daily in 2 divided doses.
Child 2–12 years:
Initially 600 micrograms/kg/day in 2 divided doses for 14 days, then 1.2 mg/kg/day in 2 divided doses for further 14 days, thereafter increased by maximum 1.2 mg/kg/day in every 7–14 days; usual maintenance 5–15 mg/kg/day in 2 divided doses (maximum 400 mg/day in 2 divided doses).
3. a. Monotherapy therapy of bipolar disorder (without enzyme inducing Drugs) without Valproate (adult over 18 years)
Initially 25 mg once daily for 14 days, then 50 mg once daily for further 14 days, then 100 mg once daily for further 7 days; usual maintenance dose 200 mg once daily; maximum 200 mg daily.
3. b. Adjunctive therapy of bipolar disorder with valproate (adult over 18 years)
Initially 25 mg on alternate days for 14 days, then 25 mg once daily for further 14 days, then 50 mg once daily for further 7 days; usual maintenance dose 100 mg daily; maximum 100 mg daily.
3. c. Adjunctive therapy of bipolar disorder (with enzyme inducing drugs with enzyme inducing drugs e.g., Carbamazepine, Phenytoin, Phenobarbital, or Primidone) without Valproate (adult over 18 years)
Initially 50 mg once daily for 14 days, then 50 mg twice daily for further 14 days, then 100 mg twice daily for further 7 days, then 150 mg twice daily for further 7 days; usual maintenance 200 mg twice daily.

ADVERSE REACTIONS

Adult: Dizziness, headache, diplopia, ataxia, nausea, blurred vision, somnolence, rhinitis, pharyngitis, and rash.
Children: Vomiting, diarrhea, infection, fever, abdominal pain, and tremor.

SPECIAL WARNINGS AND PRECAUTIONS

- Discontinue at the first sign of rash.
- Blood dyscrasias (e.g., neutropenia, thrombocytopenia, pancytopenia): May occur, either with or without an associated hypersensitivity syndrome. Monitor for signs of anemia, unexpected infection, or bleeding.
- Suicidal behavior and ideation: Monitor for suicidal thoughts or behaviors.
- Aseptic meningitis: Monitor for signs of meningitis.

CONTRAINDICATIONS

Hypersensitivity (e.g., rash, angioedema, acute urticaria, extensive pruritus, mucosal ulceration) to the drug or its ingredients.

DRUG INTERACTIONS

- Valproate increases lamotrigine concentrations more than 2-fold.
- Carbamazepine, phenytoin, phenobarbital, primidone, and rifampin decrease lamotrigine concentrations by approximately 40%.
- Estrogen-containing oral contraceptives decrease lamotrigine concentrations by approximately 50%.
- Protease inhibitors lopinavir/ritonavir and atazanavir/lopinavir decrease lamotrigine exposure by approximately 50% and 32%, respectively.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy category C.
Nursing Mothers: Lamotrigine is present in milk from lactating women taking Lamotrigine.
Hepatic impairment: Dosage adjustments required in patients with moderate and severe liver impairment.
Renal impairment: Reduced maintenance doses may be effective for patients with significant renal impairment.

STORAGE

Protect from light and moisture, store below 300 C. Keep out of the reach of children

HOW SUPPLIED

Lamicet™ 50 Tablet: Box containing 10/20/30/50 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH