خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،
روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دُور رکھیں۔

Manufactured by:
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Mfg. Lic. 000415

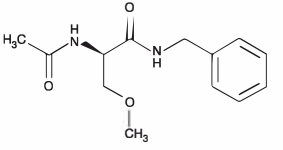
QAR No. AW22-1017

VIMLOC
(Lacosamide)

ویملوک

50 mg & 100 mg Tablets

DESCRIPTION: The chemical name of lacosamide, The single (R)-enantiomer, is (R)-2-acetamido-N-benzyl-3- methoxypropionamide (IUPAC). Lacosamide is a functionalized amino acid. Its molecular formula is $C_{13}H_{18}N_2O_3$ and its molecular weight is 250.30. The chemical structure is:



Lacosamide is a white to light yellow powder. It is sparingly soluble in water and slightly soluble in acetonitrile and ethanol.

COMPOSITION:

VIMLOC 50mg Tablets
Each film coated tablet contains:
Lacosamide 50mg

VIMLOC 100mg Tablets
Each film coated tablet contains:
Lacosamide 100mg

CLINICAL PHARMACOLOGY:

Mechanism of Action: The precise mechanism by which Lacosamide exerts its antiepileptic effects in humans remains to be fully elucidated. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes and inhibition of repetitive neuronal firing.

Pharmacodynamics:

Cardiac Electrophysiology: Electrocardiographic effects of Lacosamide were determined in a double-blind, randomized clinical pharmacology trial of 247 healthy subjects. Chronic oral doses of 400 and 800 mg/day were compared with placebo and a positive control (400 mg moxifloxacin). Lacosamide did not prolong QTc interval and did not have a dose-related or clinically important effect on QRS duration. Lacosamide produced a small, dose-related increase in mean PR interval. At steady-state, the time of the maximum observed mean PR interval corresponded with tmax. The placebo-subtracted maximum increase in PR interval (at tmax) was 7.3 ms for the 400 mg/day group and 11.9 ms for the 800 mg/day group. For patients who participated in the controlled trials, the

placebo-subtracted mean maximum increase in PR interval for a 400 mg/day Lacosamide dose was 3.1 ms in patients with partial-onset seizures and 9.4 ms for patients with diabetic neuropathy.

Pharmacokinetics: The pharmacokinetics of lacosamide have been studied in healthy adult subjects (age range 18 to 87), adults with partial-onset seizures, adults with diabetic neuropathy, and subjects with renal and hepatic impairment. Lacosamide is completely absorbed after oral administration with negligible first-pass effect with high absolute bioavailability of approximately 100%. The maximum lacosamide plasma concentrations occur approximately 1 to 4 hours post-dose after oral dosing, and elimination half-life is approximately 13 hours. Steady state plasma concentrations are achieved after 3 days of twice daily repeated administration. Pharmacokinetics of Lacosamide are dose proportional (100-800mg) and time invariant, with low inter- and intra-subject variability. Compared to lacosamide, the major metabolite, O-desmethyl metabolite, has a longer Tmax (0.5 to 12 hours) and elimination half-life (15-23 hours).

Absorption and Bioavailability: Lacosamide is completely absorbed after oral administration. The oral bioavailabitlity of lacosamide tablets is approximately 100%. Food does not affect the rate and extent of absorption.

Distribution: The volume of distribution is approximately 0.6 L/kg and thus close to the volume of total body water. Lacosamide is less than 15% bound to plasma proteins.

Metabolism and Elimination: Lacosamide is primarily eliminated from the systemic circulation by renal excretion and biotransformation.

The elimination half-life of the unchanged drug is approximately 13 hours and is not altered by different doses,multiple dosing or intravenous administration.

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Lacosamide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: The effects of Lacosamide on labor and delivery in pregnant women are unknown.

Nursing Mothers: It is not known whether Lacosamide is excreted in human milk. Because many drugs are excreted into human milk, a decision should be made whether to discontinue nursing or to discontinue Lacosamide, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and effectiveness of Lacosamide in pediatric patients below 1 month of age have not been established.

Geriatric Use: There were insufficient numbers of elderly patients enrolled in partial-onset seizure trials (n=18) to adequately determine weather they respond differently from younger patients.

Renal Impairment:

In all patients with renal impairment, dose titration should be performed with caution.

Hepatic Impairment:

The pharmacokinetics of lacosamide has not been evaluted in severe hepatic impairment Lacosomide use is not recommended in patients with severe hepatic impairment.

INDICATIONS AND USAGE:

Partial-Onset Seizures: Lacosomide is indicated for the treatment of partial-onset seizures in pateints 1 month of age and older.

Primary Generalized Tonic-Clonic Seizures: Lacosomide is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

DOSAGE AND ADMINISTRATION (Oral):

Adults (17 years and older):

Initial dosage for monotherapy for the treatment of partial-onset seizures is 100 mg twice daily.

Initial dosage for adjunctive therapy for the treatment of partial-onset seizures or primary generalized tonic-clonic seizures is 50 mg twice daily.

Maximum recommended dosage for monotherapy and adjunctive therapy is 200 mg twice daily.

Pediatric Patients 1 month to less than 17 years: The recommended dosage is based on body weight and is administered orally twice daily.

Increase dosage based on clinical response and tolerability, no more frequently than once per week

ADVERSE REACTIONS:

Adjunctive therapy: Most common adverse reactions in adults (≥10% and greater than placebo) are diplopia, headache, dizziness, nausea, and somnolence.

Monotherapy: Most common adverse reactions are similar to those seen in adjunctive therapy studies.

Pediatric patients: Adverse reactions are similar to those seen in adult patients.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS:

Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including Lacosamide, 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.

Dizziness and Ataxia: Lacosamide may cause dizziness and ataxia in adult and pediatric patients.

Cardiac Rhythm and Conduction Abnormalities: Obtaining ECG before beginning and after titration to steady-state maintenance is recommended in patients with underlying proarrhythmic conditions or on concomitant medications that affect cardiac conduction; closely monitor these patients

STORAGE:

Store below 30° C in a dry place, protect from light. To be dispensed on the prescription of a registered medical practitioner only. Keep out of the reach of children.

PRESENTATION:

VIMLOC 50mg tablets are available in Alu-Alu blister pack of 2x7's.

VIMLOC 100mg tablets are available in Alu-Alu blister pack of 2x7's.