# VICOMID

(Lacosamide) Tablets, BP

# ویکومڈ

(لیکوسامائیڈ) ٹیبلیٹس

**COMPOSITION:**
**Vicomid tablets 50mg:**
Each film coated tablet contains: Lacosamide BP ... 50mg. [BP Specs.]
**Vicomid tablets 100mg:**
Each film coated tablet contains: Lacosamide BP ... 100mg. [BP Specs.]

**DESCRIPTION:**
The chemical name of lacosamide, The single (R)-enantio- mer, 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 250.30g/mol. Lacosamide is a white to light yellow powder. It is sparingly soluble in water and slightly soluble in acetonitrile and ethanol.

**INDICATIONS:**
**Partial-Onset Seizures: Vicomid** is indicated as a monotherapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older.

**DOSAGE AND ADMINISTRATION:**
Lacosamide may be taken with or without food.
**Partial-Onset Seizures: Vicomid** can be initiated with either oral or intravenous administration. The initial dose should be 50mg twice daily (100mg per day). **Vicomid** can be increased at weekly intervals by 100mg/day given as two divided doses up to the recommended maintenance dose of 200 to 400mg/day, based on individual patient response and tolerability.
**Patients with Renal Impairment:** No dose adjustment is necessary in patients with mild to moderate renal impairment. A maximum dose of 300mg/day Lacosamide is recommended for patients with severe renal impairment [creatinine clearance (CLCR) ≤ 30ml/min] and in patients with end stage renal disease. Lacosamide is effectively removed from plasma by hemodialysis. Following a 4-hour hemodialysis treatment, dosage supplementation of up to 50% should be considered. In all renal impaired patients, the dose titration should be performed with caution.
**Patients with Hepatic Impairment:** The dose titration should be performed with caution in patients with hepatic impairment. A maximum dose of 300mg/day is recommended for patients with mild or moderate hepatic impairment. Lacosamide use is not recommended in patients with severe hepatic impairment.

**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 hyper excitable neuronal membranes and inhibition of repetitive neuronal firing. Lacosamide binds to collapsin response mediator protein-2 (CRMP-2), a phosphoprotein which is mainly expressed in the nervous system and is involved in neuronal differentiation and control of axonal outgrowth. The role of CRMP-2 binding in seizure control is unknown.

**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 400mg and 800mg/day were compared with placebo and a positive control (400mg 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 800mg/day group. For patients who participated in the controlled trials, the placebo-subtracted mean maximum increase in PR interval for a 400mg/day Lacosamide dose was 3.1 ms in patients with partial-onset seizures and 9.4ms for patients with diabetic neuropathy.
**Pharmacokinetics:** The pharmacokinetics of **Vicomid** 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%.

Rev: 06-22/1

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 12hours) and elimination half-life (15-23 hours).

**Metabolism and Elimination:** Lacosamide is primarily eliminated from the systemic circulation by renal excretion and biotransformation. After oral and intravenous administration of 100mg Lacosamide approximately 95% of radioactivity administered was recovered in the urine and less than 0.5% in the feces. The major compounds excreted were unchanged Lacosamide (approximately 40% of the dose), its O-desmethyl metabolite (approximately 30%), and a structurally unknown polar fraction (~20%). The plasma exposure of the major human metabolite, O-desmethyl-lacosamide, is approximately 10% of that of Lacosamide. This metabolite has no known pharmacological activity. Lacosamide is a CYP2C19 substrate. The relative contribution of other CYP isoforms or non-CYP enzymes in the metabolism of Lacosamide is not clear. The elimination half-life of the unchanged drug is approximately 13 hours and is not altered by different doses,multiple dosing or intravenous administration. There is no enantiomeric interconversion of Lacosamide
**Pregnancy Category C:** 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 in to account the importance of the drug to the mother.
**Paediatric Use:** Lacosamide is not recommended for use in children & adolescents below the age of 16.
**Geriatric Use:** Caution should be exercised for dose titration in elderly patients

**CONTRAINDICATION:** Hypersenstivity of any ingredients of drug.

**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:** Treatment with Lacosamide has been associated with dizziness which could increase the occurrence of accidental injury or falls.
**Cardiac Rhythm and Conduction:** Lacosamide should be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure. Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheaded and fainting) and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath). Patients should be counseled to seek medical advice should any of these symptoms occur

**INSTRUCTIONS:** Store below 30° C. Protect from heat, light and moisture. Keep out of the reach of children.

**PRESENTATION:**
**Vicomid** tablets 50mg are available in pack of 14's.
**Vicomid** tablets 100mg are available in pack of 14's

**ہدایات:** ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
**NABIQASIM INDUSTRIES (PVT.) LTD.**
PHARMA 17/24, Korangi Industrial Area, Karachi-Pakistan.

Rev: 06-22/1