Lacomax™

Lacosamide BP Tablet and Oral Solution

Presentation
Lacomax™ 50 Tablet: Each tablet contains Lacosamide BP 50 mg.
Lacomax™ 100 Tablet: Each tablet contains Lacosamide BP 100 mg.
Lacomax™ Oral Solution: Each 5 ml solution contains Lacosamide BP 50 mg.

Description
The precise mechanism by which Lacosamide exerts its anti-epileptic 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.

Indications and usage
Lacosamide is indicated for the treatment of partial-onset seizures in patients 1 month of age and older. Lacosamide is indicated for adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

Dosage and administration
Table-1: Recommended Dosages for Partial-Onset Seizures (Monotherapy or Adjunctive Therapy) in Patients 1 Month and Older, and for Primary Generalized Tonic-Clonic Seizures (Adjunctive Therapy) in Patients 4 Years of Age and Older

<table>
<tr><th>Age and Body Weight</th><th>Initial Dosage</th><th>Titration (Incremental Steps)</th><th>Maintenance Dosage</th></tr>
<tr><td>Adults (≥ 17 years)</td><td>Monotherapy:
100 mg twice daily
(200 mg per day)
Adjunctive therapy:
50 mg twice daily
(100 mg per day)</td><td rowspan="2">Increase by 50 mg twice daily
(100 mg per day) every week</td><td>Monotherapy:
150 - 200 mg twice daily
(300 - 400 mg per day)
Adjunctive therapy:
100 - 200 mg twice daily
(200 - 400 mg per day)</td></tr>
<tr><td>Pediatric patients (≥ 50 kg)</td><td>50 mg twice daily
(100 mg per day)</td></tr>
<tr><td>Pediatric patients (30 - 50 kg)</td><td rowspan="3">1 mg/kg twice daily
(2 mg/kg per day)</td><td rowspan="3">Increase by 1 mg/kg twice daily
(2 mg/kg/day) every week</td><td>2 - 4 mg/kg twice daily
(4 - 8 mg/kg/day)</td></tr>
<tr><td>Pediatric patients (6 - 30 kg)</td><td>3 - 6 mg/kg twice daily
(6 - 12 mg/kg/day)</td></tr>
<tr><td>Pediatric patients (< 6 kg)</td><td>3.75 - 7.5 mg/kg twice daily
(7.5 - 15 mg/kg/day)</td></tr>
</table>

Lacosamide tablets and oral solution may be taken with or without food.

Side-effects
The most common adverse reactions of Lacosamide are dizziness, headache, somnolence, ataxia, tremor, nausea, vomiting, fatigue, diplopia, blurred vision etc.

Contraindications
Laocsamide is contraindicated in patients with a known hypersensitivity to either Laocsamide or to any excipients in Laocsamide.

Precautions
Monitor patients for Suicidal behavior, Dizziness, Ataxia, PR interval prolongation, Atrioventricular block, Ventricular tachyarrhythmia, Atrial fibrillation, Atrial flutter, Syncope, Phenylketonuria, Multi-organ hypersensitivity etc. when Lacosamide is prescribed.

Drug interactions
Dose reduction of Lacosamide may be necessary in patients with renal or hepatic impairment who are taking strong inhibitors of CYP3A4 & CYP2C9. Lacosamide should be used with caution in patients who are on concomitant medications that affect cardiac conduction (sodium channel blockers, beta-blockers, calcium channel blockers, potassium channel blockers) including those that prolong PR interval (sodium channel blocking AEDs).

Use in pregnancy and lactation
Pregnancy: There are no adequate and well-controlled studies in pregnant women and Lacosamide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: Lacosamide is excreted in human breast milk. The known benefits of breastfeeding should be weighed against the unknown risks of infant exposure to Lacosamide.

Use in special population
Pediatric use: Safety and effectiveness of Lacosamide have not been established in pediatric patients below 1 month of age in partial onset seizures and 4 years in primary generalized tonic clonic seizures.
Geriatric use: Start at the lower end of the dosing range.
Renal impairment: No dose adjustment is necessary in patients with mild to moderate renal impairment. In patients with severe renal impairment and end stage renal disease, a reduction of 25% of the maximum dosage is recommended.
Hepatic impairment: Patients with mild to moderate hepatic impairment, a reduction of 25% of the maximum dosage is recommended. Lacosamide use is not recommended in patients with severe hepatic impairment.

Overdose
There is no specific antidote for overdose with Lacosamide. If overdose occurs general supportive and symptomatic measures should be employed.

Storage
Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack
Lacomax™ 50 Tablet: Each box contains 3 blister strips of 10 tablets.
Lacomax™ 100 Tablet: Each box contains 2 blister strips of 10 tablets.
Lacomax™ Oral Solution: Each bottle contains 50 ml of Lacosamide oral solution.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
™ Trademark