EPICOS®

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1. **Product Name**
EPICOS® 50 mg Film Coated Tablet BP
EPICOS® 100 mg Film Coated Tablet BP

2. **Name and Strength of Active Ingredient (s)**
EPICOS® 50 mg:
Each Film Coated Tablet contains
Lacosamide BP 50 mg
EPICOS® 100 mg:
Each Film Coated Tablet contains
Lacosamide BP 100 mg

3. **Product Description**
Lacosamide is a functionalized amino acid indicated for the adjunctive treatment of partial-onset seizures and as adjunctive therapy for primary generalised tonic-clonic seizures.

4. **Pharmacodynamics & Pharmacokinetics**
Pharmacodynamics:
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.
Lacosamide binds to collapsin response mediator protein-2 (CRMP-2), a phosphoprotein which is expressed primarily in the nervous system and is involved in neuronal differentiation and control of axonal outgrowth. The role of CRMP-2 binding in seizure control hasn't been elucidated.
Pharmacokinetics:
Lacosamide is rapidly and completely absorbed after oral administration. The oral bioavailability of lacosamide tablets is approximately 100%. Following oral administration, the plasma concentration of unchanged lacosamide increases rapidly and reaches C_{max} about 0.5 to 4 hours post-dose. Food does not affect the rate and extent of absorption.
The volume of distribution is approximately 0.6 L/kg. Lacosamide is less than 15% bound to plasma proteins.
95% of the dose is excreted in the urine as lacosamide and its metabolites. The major compounds excreted in urine are unchanged lacosamide (approximately 40% of the dose) and its *O*-desmethyl metabolite less than 30%.
Lacosamide is primarily eliminated from the systemic circulation by renal excretion and biotransformation. The elimination half-life of lacosamide is approximately 13 hours.

5. **Indications**
Partial-onset seizures: Tablets are indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

6. **Recommended Dose and Administration**
- **Adults (17 years and older):** Initial dosage for monotherapy is 100 mg twice daily; initial dosage for adjunctive therapy is 50 mg twice daily; maximum recommended dosage for monotherapy and adjunctive therapy is 200 mg twice daily.
- **Pediatric Patients 4 Years 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.
- Dose adjustment is recommended for severe renal impairment.
- Dose adjustment is recommended for mild or moderate hepatic impairment; use in patients with severe hepatic impairment is not recommended

7. **Contraindication**
Contraindicated in patients with known hypersensitivity to lacosamide or any of its components.

8. **Warnings and Precautions**
- Suicidal Ideation and Behavior
- Cardiac Rhythm and Conduction Abnormalities
- Dizziness and Ataxia
- Syncope
- Withdrawal Symptoms of Antiepileptic Drugs (AEDs)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multi-Organ Hypersensitivity
- Risks in Patients with Phenylketonuria

9. **Drug Interactions**
Strong CYP3A4 or CYP2C9 Inhibitors:
Patients with renal or hepatic impairment who are taking strong inhibitors of CYP3A4 and CYP2C9 may have a significant increase in exposure to Lacosamide. Dose reduction may be necessary in these patients.
Concomitant Medications that Prolong PR Interval:
Lacosamide should be used with caution in patients on concomitant medications that prolong PR interval, because of a risk of AV block or bradycardia, e.g., beta-blockers and calcium channel blockers. In such patients, obtaining an ECG before beginning Lacosamide, and after Lacosamide is titrated to steady-state, is recommended.

10. **Pregnancy and Lactation**
Pregnancy:
There are no adequate data on the developmental risks associated with the use of lacosamide in pregnant women.
Lactation:
There are no data on the presence of lacosamide in human milk, the effects on the breastfed infant, or the effects on milk production. Studies in lactating rats have

shown excretion of lacosamide and/or its metabolites in milk.

11. Side Effects

The most common side effects of lacosamide in adults include:

- Double vision
- Headache
- Dizziness
- Nausea

12. Overdose and Treatment

Symptoms:

Symptoms observed after an accidental or intentional overdose of lacosamide are primarily associated with CNS and gastrointestinal system.

The types of adverse reactions experienced by patients exposed to doses above 400 mg up to 800 mg were not clinically different from those of patients administered recommended doses of lacosamide.

Reactions reported after an intake of more than 800 mg are dizziness, nausea, vomiting, seizures (generalised tonic-clonic seizures, status epilepticus). Cardiac conduction disorders, shock and coma have also been observed. Fatalities have been reported in patients following an intake of acute single overdose of several grams of lacosamide.

Management:

There is no specific antidote for overdose with lacosamide. Treatment of lacosamide overdose should include general supportive measures and may include haemodialysis if necessary.

13. Storage Condition

Store EPICOS® below 30ºC at cool and dry place, away from light and moisture. Keep the medication away from children and pets.

14. Dosage Forms and Packaging Available

EPICOS® 50 Tablets: Each Box contains 30 Tablets X 5 Blisters

EPICOS® 100 Tablets: Each Box contains 30 Tablets X 5 Blisters

Manufactured by:
Deurali-Janta Pharmaceuticals Pvt. Ltd.
679, Budhanilkantha Sadak, Bansbari - 03 | G.P.O. Box: 4239,
Kathmandu, Nepal Tel: +977-01- 4018777
E-mail: mplanning@deuralijanta.com, Website: www.deuralijanta.com
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