For The Use of A Registered Medical Practitioner or A Hospital or A Laboratory

Rx Lacosamide Injection USP

AMERICAN
COSEPIL
Injection

DESCRIPTION
Lacosamide is an antiepileptic drug used to treat seizures. As a chiral functionalized amino acid, it works by blocking slowly inactivating components of voltage-gated sodium currents. Lacosamide exhibits a stereoselective mode of interaction with sodium channels.

PHARMACEUTICAL FORM
Solution for injection.
Clear, colourless to pale yellow, sterile solution for IV use.

Therapeutic Classification
An anticonvulsant or anti-epileptic drug (AED)

Composition :
Each ml contains:
Lacosamide USP…….....10 mg
Water for Injection I.P…… Q.S.

INDICATIONS AND USAGE
For temporary treatment of partial-onset seizures and as adjunctive therapy for primary generalized tonic-clonic seizures (PGTC) in patients unable to take oral medication, working by stabilizing electrical activity in the brain

CONTRAINDICATIONS
Hypersensitivity to the active substance or to peanuts or soya or to any of the excipients.
Known second- or third-degree atrioventricular (AV) block.

WARNINGS & PRECAUTIONS
Treatment with lacosamide has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine.

Prolongations in PR interval with lacosamide have been observed in clinical studies. 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. Caution should especially be exerted when treating elderly patients as they may be at an increased risk of cardiac disorders or when lacosamide is used in combination with products known to be associated with PR prolongation.

Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications. A meta-analysis of randomised placebo-controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for lacosamide. Therefore, patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

POSSIBLE SIDE EFFECTS
Lacosamide Injection may cause certain side effects. Consult your doctor for medical advice on persisting side effects.

- nausea
- vomiting
- diarrhea
- dry mouth
- numbness or tingling in the mouth
- blurred or double vision
- uncontrollable eye movements
- dizziness
- headache
- drowsiness
- uncontrollable shaking of a part of the body
- problems with coordination, balance, or walking
- weakness
- itching
- redness, irritation, pain, or discomfort at the injection spot

DRUG INTERACTIONS
Always inform your doctor about all medications, supplements, and alcohol use when taking lacosamide.

Lacosamide injections have significant interactions, primarily with drugs affecting heart rhythm (beta-blockers, calcium channel blockers, other sodium/potassium channel blockers) due to increased risk of AV block/bradycardia, requiring ECG monitoring

OVER DOSE

- **Neurological:** Dizziness, confusion, drowsiness, seizures (including status epilepticus), coma, agitation, tremors, altered consciousness.
- **Cardiovascular:** Slow heart rate (bradycardia), irregular heartbeat, fainting (syncope), wide QRS complex on ECG, shock, cardiac arrest, atrial fibrillation, bundle branch block.
- **Other:** Vomiting, potential for aspiration, respiratory depression.

DOSAGE AND ADMINISTRATION
Lacosamide injections is administered intravenously (IV) as recommended by a healthcare professional.
Lacosamide injections shall be administered by the doctor or healthcare professional in a medical setting.
Do not self-administer.

PRESENTATION
20ml in glass vial

STORAGE
Store at temperature not exceeding 30°C.
Do not freeze.

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