ABRIDGED PRESCRIBING INFORMATION: LACOTIDE (Tabs & Injection)

Active Ingredient: Tablet: Each Lacotide 50 / 100 / 150 / 200 tablet contains Lacosamide 50mg, 100mg, 150mg, 200mg. Injection: Each ml contains Lacosamide 10 mg.
Indications: Lacosamide is indicated as monotherapy, and adjunctive therapy for treatment of partial-onset seizures in patients with epilepsy aged 17 years and older. **Dosage and administration:** (i) Monotherapy: The initial recommended dose of LACOTIDE is 100 mg twice daily; based on individual patient response and tolerability; the dose should be increased at weekly intervals by 50mg twice daily, up to a recommended maintenance dose of 150 mg to 200 mg twice daily. (ii) Adjunctive therapy: The initial recommended dose of LACOTIDE is 50 mg twice daily; based on individual patient response and tolerability; the dose should be increased at weekly intervals by 50 mg twice daily, up to a recommended maintenance dose of 100 mg to 200 mg twice daily. Switching from Oral to IV Dosing / IV to Oral Dosing: When switching, the initial total daily intravenous dosage of Lacotide should be equivalent to the total daily dosage. Injection administration: Lacotide Inj. can be administered intravenously without further dilution or may be mixed with diluents. It is given by infusion over 15 to 60 minutes. **Contraindications:** Hypersensitivity. Known second-or third-degree artrioventricular (AV) block. **Warnings and Precautions:** Suicidal Behavior and Ideation: Patient 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: Patients should be advised not to drive a car or to operate other complex machinery until they are familiar with the effects of lacosamide on their ability to perform such activities. Cardiac Rhythm and Conduction Abnormalities. Withdrawal of Antiepileptic Drugs (AEDs**):** Lacosamide should be withdrawn gradually (over a minimum of 1 week). **Multiorgan Hypersensitivity Reactions:** If this reaction is suspected, Lacotide should be discontinued and alternative treatment started. **Use in Specific Populations:** Pregnancy: Pregnancy Category C. Lacotide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Labor and Delivery: The effects of Lacotide on labor and delivery in pregnant women are unknown. Nursing Mothers: It is not known whether lacosamide is excreted in human milk. Pediatric Use: The safety and effectiveness of Lacotide in pediatric patients <17 years have not been established. Geriatric Use: No Lacotide dose adjustment based on age is considered necessary. Caution should be exercised for dose titration in elderly patients. **Drug Interactions:** None. **Adverse Reactions:** Adverse events most commonly leading to discontinuation are dizziness, ataxia, vomiting, diplopia, nausea, vertigo and vision blurred. **Overdose:** There is limited clinical experience with Lacotide overdose in humans. There is no specific antidote for overdose with Lacotide. **FOR FURTHER INFORMATION, PLEASE REFER FULL PRESCRIBING INFORMATION**

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