Abridged Prescribing Information:

Active Ingredient: Levera tablet contains levetiracetam 250mg/500mg/750mg/1000mg ; Levera XR tablet contains levetiracetam extended release 500mg / 750mg / 1000mg; Levera DT is dispersible tablet contains levetiracetam 250 mg and 500 mg; Levera Injection contains Levetiracetam 100mg/ml inj; Levera RTU Each 100 mL Infusion Bottle contains levetiracetam 500/1000/1500 mg. Levera solution contain levetiracetam 100mg/ml solution

Indication: For Levera, Levera XR, Levera DT, Levera Solution- (i) As monotherapy in partial onset seizures with or without secondary generalisation in patients with 16 years of age with newly diagnosed epilepsy. (ii) As adjunctive therapy in myoclonic seizures in adults and adolescents from 12 years of age with Juvenile myoclonic epilepsy. In primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy. **For Levera Inj & RTU:** as adjunctive therapy when oral administration is temporarily not feasible in adults (16 years and older) with the following types of seizures: Partial onset seizures, Myoclonic seizures in patients with juvenile myoclonic epilepsy, Primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy & status epilepticus. **Dosage & Administration**: **Levera, Levera XR, Levera DT, Levera Solution-** for Partial Onset Seizures, Adults 16 Years and Older: Treatment should be initiated with a daily dose of 1000 mg/day, given as twice-daily dosing (500 mg BID). Additional dosing increments may be given (1000 mg/day additional every 2 weeks) to a maximum recommended daily dose of 3000 mg. Pediatric Patients Ages 4 to <16 Years: Treatment should be initiated with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg BID). The daily dose should be increased every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg BID). If a patient cannot tolerate a daily dose of 60 mg/kg, the daily dose may be reduced. **Levera Inj & RTU -** Treatment should be initiated with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg BID). The daily dose should be increased every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg BID). If a patient cannot tolerate a daily dose of 60 mg/kg, the daily dose may be reduced. Levera RTU is for intravenous use only, do not dilute prior to its use, Administer dose-specific 100 mL infusion bottle intravenously over 15-minutes. **Contraindication:** Levetiracetam is contraindicated in patients with known hypersensitivity to levetiracetam or any of the inactive ingredients in levetiracetam tablets. **Warnings & Precautions:** Levetiracetam use is associated with the occurrence of central nervous system adverse events that can be classified into the following categories: 1) Somnolence and Fatigue, 2) Coordination Difficulties and 3) Behavioral Abnormalities. Withdrawal: Antiepileptic drugs, including levetiracetam, should be withdrawn gradually to minimize the potential of increased seizure frequency. PRECAUTIONS: Hematologic Abnormalities: Levetiracetam treated patients showed minor, but statistically significant, decreases in total mean RBC count, mean hemoglobin and mean hematocrit. Hepatic Abnormalities: In epilepsy patient receiving open treatment, there were no meaningful changes in mean Liver Function Tests (LFT) in controlled trials; lesser LFT abnormalities were seen. **Pregnancy:** Pregnancy Category C. LABOR AND DELIVERY: The effect of levetiracetam on labor and delivery in humans is unknown. **Specific Population: GERIATRIC USE:** Levetiracetam is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. Use in Patients with Impaired **Renal Function:** Clearance of levetiracetam is decreased in patients with renal impairment and is correlated with creatinine clearance. The dosage should be reduced in patients with impaired renal function receiving levetiracetam and supplemental doses should be given to patients after dialysis Adverse **Reactions:** The most frequently reported adverse events associated with the use of levetiracetam in combination with other AEDs, were somnolence, asthenia, infection and dizziness. **Overdose:** The highest known dose of levetiracetam received in the clinical development program was 6000 mg/day. Other than drowsiness, there were no adverse events in the few known cases of overdose.

(For details, please refer full prescribing information)

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productqueries@intaspharma.com