

Leviceta

Levetiracetam Tablet

Composition

Leviceta 250 Tablet: Each film coated tablet contains Levetiracetam USP 250 mg

Leviceta 500 Tablet: Each film coated tablet contains Levetiracetam USP 500 mg

Pharmacology

Levetiracetam is a novel antiepileptic drug. It acts by binding to the Synaptic Vesicle Protein (SV2A) which is present on synaptic vesicles and some neuroendocrine cells. Pharmacokinetics of Levetiracetam such as less protein binding and lack of hepatic metabolism make Levetiracetam less susceptible to drug interactions with other anticonvulsants.

Indications

Levetiracetam is indicated for monotherapy and adjunctive treatment of focal seizures with or without secondary generalization and for adjunctive therapy of myoclonic seizures in patients with juvenile myoclonic epilepsy and primary generalized tonic-clonic seizures.

Dose and Administration

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.

Monotherapy of focal seizures

ADULT and CHILD over 16 years: Initially 250 mg once daily increased after 1–2 weeks to 250mg twice daily. Thereafter, increased according to response in steps of 250mg twice daily every 2 weeks; max. 1.5 g twice daily.

Adjunctive therapy of focal seizures

CHILD 1–6 months: Initially 7 mg/kg once daily, increased by max. 7 mg/kg twice daily every 2 weeks; max. 21 mg/kg twice daily.

CHILD over 6 months, body-weight under 50 kg: Initially 10 mg/kg once daily, increased by max. 10 mg/kg twice daily every 2 weeks; max. 30 mg/kg twice daily.

ADULT and CHILD over 12 years body-weight over 50 kg: Initially 250 mg twice daily, increased by 500mg twice daily every 2–4 weeks; max. 1.5 g twice daily.

Adjunctive therapy of myoclonic seizures and generalized tonic-clonic seizures

ADULT and CHILD over 12 years, body-weight over 50 kg: Initially 250 mg twice daily, increased by 500 mg twice daily every 2–4 weeks; max. 1.5 g twice daily.

CHILD 12–18 years, body-weight under 50 kg: Initially 10 mg/kg once daily, increased by max. 10 mg/kg twice daily every 2 weeks; max. 30 mg/kg twice daily.

Dosing Adjustment Regimen for Patients with Impaired Renal Function:

Severity	Creatinine Clearance (mL/min)	Dosage (mg)	Frequency
Normal	>80	500 - 1,500	Every 12 h
Mild	50-80	500 - 1,000	Every 12 h
Moderate	30-50	250 - 750	Every 12 h
Severe	<30	250 - 500	Every 12 h
ESRD patients using dialysis	—	500 - 1,000	Every 24 h

*ESRD- End Stage Renal Disease, *Following dialysis, a 250-500 mg supplemental dose is recommended

Contraindications

Levetiracetam is contraindicated in patients who have previously exhibited hypersensitivity to Levetiracetam or any of the inactive ingredients in tablets.

Precautions

Severe allergic reactions, abnormal thoughts, dark urine, decreased coordination, extreme dizziness, drowsiness, tiredness or weakness, fever, chills, persistent sore throat, hallucinations, memory loss, mouth sores, muscle or neck pain, new or worsening mental problem, mood or behavior changes, new or worsening seizures, pain, itching or redness at the injection site, suicidal thoughts or attempts, unusual bruising or bleeding, vision changes and yellowing of the skin or eyes.

Side Effects

Dizziness, drowsiness, irritability, sore throat, tiredness and weakness are some common adverse effects. In rare cases severe allergic reaction may happen.

Use in Pregnancy & Lactation

Pregnancy: Category C

Lactation: No data on the use of Levetiracetam in breast-feeding women are available. Data from animals indicate that Levetiracetam is secreted into milk. Therefore Levetiracetam is contraindicated during feeding.

Drug Interactions

No potential drug interaction has been reported.

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.

Storage

Store below 30°C and dry place, away from light. Keep out of the reach of children.

Packing

Leviceta 250 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Leviceta 500 Tablet: Each box contains 2 blister packs with each blister of 10 tablets.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.

Mouchak, Kaliakair, Gazipur, Bangladesh

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