Levetam™

Levetiracetam USP Film Coated Tablet

DESCRIPTION

Levetam™ is a preparation of Levetiracetam. The precise mechanism by which Levetiracetam exerts its antiepileptic effect is unknown. The antiepileptic activity of Levetiracetam was assessed in a number of animal models of epileptic seizures. Levetiracetam did not inhibit single seizures induced by maximal stimulation with electrical current or different chemoconvulsants and showed only minimal activity in submaximal stimulation and in threshold tests. Protection was observed, however, against secondarily generalized activity from focal seizures induced by pilocarpine and kainic acid, two chemoconvulsants that induce seizures that mimic some features of human complex partial seizures with secondary generalization. Levetiracetam also displayed inhibitory properties in the kindling model in rats, another model of human complex partial seizures, both during kindling development and in the fully kindled state. The predictive value of these animal models for specific types of human epilepsy is uncertain.

INDICATIONS

- Partial onset seizures in patients one month of age and older with epilepsy.
- Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy.
- Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

DOSAGE AND ADMINISTRATION

Partial Onset Seizures

- 4 Years to < 16 Years: 10 mg/kg twice daily; increase by 10 mg/kg twice daily every 2 weeks to recommended dose of 30 mg/kg twice daily.
- Adults 16 Years and Older: 500 mg twice daily; increase by 500 mg twice daily every 2 weeks to a recommended dose of 1500 mg twice daily.

Myoclonic Seizures in Adults and Pediatric Patients 12 Years and Older

- 500 mg twice daily; increase by 500 mg twice daily every 2 weeks to recommended dose of 1500 mg twice daily.

Primary Generalized Tonic-Clonic Seizures

- 6 Years to < 16 Years: 10 mg/kg twice daily, increase in increments of 10 mg/kg twice daily every 2 weeks to recommended dose of 30 mg/kg twice daily.
- Adults 16 Years and Older: 500 mg twice daily, increase by 500 mg twice daily every 2 weeks to recommended dose of 1500 mg twice daily.

Adult Patients with Impaired Renal Function

- Dose adjustment is recommended, based on the patient's estimated creatinine clearance.

CONTRAINDICATIONS

- Hypersensitivity
- Angioedema
- Anaphylaxis

SIDE EFFECTS

- Adult patients: somnolence, asthenia, infection and dizziness.
- Pediatric patients: fatigue, aggression, nasal congestion, decreased appetite, and irritability.

PRECAUTION AND WARNING

- Behavioral abnormalities including psychotic symptoms, suicidal ideation, irritability, and aggressive behavior have been observed; monitor patients for psychiatric signs and symptoms.
- Suicidal Behavior and Ideation: Monitor patients for new or worsening depression, suicidal thoughts/behavior, and/or unusual changes in mood or behavior.
- Monitor for somnolence and fatigue and advice patients not to drive or operate machinery until they have gained sufficient experience on Levetiracetam.
- Withdrawal Seizures: Levetiracetam must be gradually withdrawn.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and controlled studies in pregnant women. In animal studies, Levetiracetam produced evidence of developmental toxicity, including teratogenic effects, at doses similar to or greater than human therapeutic doses. Levetiracetam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Levetiracetam is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Levetiracetam, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

PHARMACEUTICAL PRECAUTION

Store at or below 30 °C temperature. Keep away from light and wet place. Keep out of the reach of children.

PACKAGING

Levetam™ 250 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Levetiracetam USP 250 mg.

Levetam™ 500 Tablet: Box containing 2 strips of 10 tablets each. Each tablet contains Levetiracetam USP 500 mg.

SK+F

Manufactured by:

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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