

Rx

Levetiracetam Injection USP

LEVETOR™

For I.V. Infusion Use

Composition :

Each ml contains :

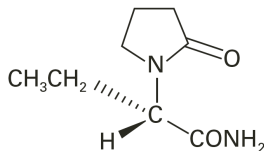
Levetiracetam IP 100 mg

Water for Injections IP q.s.

DESCRIPTION

Levetiracetam injection, USP is an antiepileptic drug available as a clear, colorless, sterile solution (100 mg/mL) for intravenous administration.

The chemical name of levetiracetam, a single enantiomer, is (-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide, its molecular formula is $C_8H_{14}N_2O_2$ and its molecular weight is 170.21. Levetiracetam is chemically unrelated to existing antiepileptic drugs (AEDs). It has the following structural formula:



Levetiracetam is a white to off-white crystalline powder with a faint odor and a bitter taste. It is very soluble in water (104.0 g/100 mL). It is freely soluble in chloroform (65.3 g/100 mL) and in methanol (53.6 g/100 mL), soluble in ethanol (16.5 g/100 mL), sparingly soluble in acetonitrile (5.7 g/100 mL) and practically insoluble in n-hexane. (Solubility limits are expressed as g/100 mL solvent.)

Levetiracetam injection contains 100 mg of levetiracetam per mL. It is supplied in single-dose 5 mL vials containing 500 mg levetiracetam, water for injection, 45 mg sodium chloride, and buffered at approximately pH 5.5 with glacial acetic acid and 8.2 mg sodium acetate trihydrate. Levetiracetam injection must be diluted prior to intravenous infusion

WARNINGS AND PRECAUTIONS

Levetiracetam may cause somnolence and fatigue. Patients should be monitored for somnolence and fatigue, and be advised not to drive or operate machinery until they have gained sufficient experience on levetiracetam to gauge whether it adversely affects their ability to drive or operate machinery.

Levetiracetam can cause anaphylaxis or angioedema after the first dose or at any time during treatment. Signs and symptoms in cases reported in the postmarketing setting have included hypotension, hives, rash, respiratory distress, and swelling of the face, lip, mouth, eye, tongue, throat, and feet. In some reported cases, reactions were life-threatening and required emergency treatment. If a patient develops signs or symptoms of anaphylaxis or angioedema, levetiracetam should be discontinued and the patient should seek immediate medical attention. Levetiracetam should be discontinued permanently if a clear alternative etiology for the reaction cannot be established

Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in both pediatric and adult patients treated with levetiracetam. The median time of onset is reported to be 14 to 17 days, but cases have been reported at least four months after initiation of treatment. Recurrence of the serious skin reactions following rechallenge with levetiracetam has also been reported. Levetiracetam should be discontinued at the first sign of a rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

Levetiracetam may cause coordination difficulties.

In controlled clinical studies using an oral formulation of levetiracetam in adult patients with partial-onset seizures, 3.4% of levetiracetam-treated patients experienced coordination difficulties, (reported as ataxia, abnormal gait, or incoordination) compared to 1.6% of placebo-treated patients. A total of 0.4% of patients in controlled clinical studies discontinued levetiracetam treatment due to ataxia, compared to 0% of placebo-treated patients. In 0.7% of levetiracetam-treated patients and in 0.2% of placebo-treated patients, the dose was reduced due to coordination difficulties, while one of the treated patients was hospitalized due to worsening of pre-existing ataxia. These events occurred most frequently within the first 4 weeks of treatment.

Patients should be monitored for signs and symptoms of coordination difficulties and advised not to drive or operate machinery until they have gained sufficient experience on levetiracetam to gauge whether it could adversely affect their ability to drive or operate machinery.

CONTRAINDICATION

Levetiracetam injection is contraindicated in patients with a hypersensitivity to levetiracetam. Reactions have included anaphylaxis and angioedema

STORAGE

Keep in a cool & dry place. Protect from light, below 25°C

Mfd. by : Protech Telelinks
(A WHO-GMP Certified Co.)
Mauza Ogli, Suketi Road, Kala Amb,
District Sirmour (H.P.)173030



Manufactured in India for :
SUNFORT HEALTHCARE
(INDIA) PVT. LTD.
301, SANSKRITI - C.H.S.
KASHMIRA-MEERAROAD (EAST)
THANE-401107
(MAHARASTRA)