Only for the use of Medical Professionals

Citazar®

Levetiracetam

Description

Citazar® is a preparation of Levetiracetam, a pyrrolidone derivative, which is an antiseizure (antiepileptic) agent. It is believed to work by binding to a synaptic vesicle protein, SV2A (synaptic vesicle glycoprotein 2A) and in turn impeding nerve conduction across synapses. It inhibits the spread of seizure activity in brain.

Indication and usage

Citazar® is indicated in monotherapy and adjunctive treatment of partial seizures with or without secondary generalisation, and for adjunctive therapy of myoclonic seizures and primarily generalised tonic-clonic seizures.

Dose and administration

The recommended dose of Citazar® is as following:

Monotherapy

Adults and adolescents from 16 years of age: The recommended starting dose is 250 mg twice daily which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily every two weeks depending upon the clinical response. The maximum dose is 1500 mg twice daily.

Adjunctive therapy

Adults (≥18 years) and adolescents (12 to 17 years) weighing 50 kg or more: The initial therapeutic dose is 500 mg twice daily. This dose can be started on the first day of treatment. Depending upon the clinical response and tolerability, the daily dose can be increased up to 1500 mg twice daily.

Children aged 4 to 11 years & adolescents (12 to 17 years) weighing less than 50 kg: The initial therapeutic dose is 10 mg/kg twice daily. Depending upon the clinical response and tolerability, the dose can be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10 mg/kg twice daily every two weeks. The lowest effective dose should be used.

Use in infants and children less than 4 years: Levetiracetam is not recommended for use in children below 4 years of age due to insufficient data on safety and efficacy.

Dosage in patients with renal impairment:

Creatinine clearance	Maximum daily dose
50–80 mL/minute	2 g
30–50 mL/minute	1.5 g
30 mL/minute	1 g

Dosage in patients with hepatic impairment:
No dose adjustment is needed in patients with mild to moderate hepatic impairment.
In severe hepatic impairment if creatinine clearance is < 70 ml/min, 50% reduction of the daily maintenance dose is recommended.

Use in pregnancy and lactation:
Levetiracetam should not be used during pregnancy unless clearly necessary. Physiological changes during pregnancy may affect levetiracetam concentration. Decrease in levetiracetam plasma concentrations has been observed during pregnancy. This decrease is more pronounced during the third trimester. Levetiracetam is excreted in human breast milk. Therefore, during breast-feeding Levetiracetam is not recommended. However, if levetiracetam treatment is needed during breastfeeding, risk/benefit ratio of the treatment should be weighed considering the importance of breastfeeding.

Precautions
Levetiracetam should not be withdrawn abruptly. Patients should be monitored for signs of depression and/ or suicidal ideation.

Side effects
The common side effects of Levetiracetam are nausea, vomiting, diarrhea, anorexia, weight changes; drowsiness, asthenia, amnesia, ataxia, seizures, dizziness, headache, tremor, hyperkinesia, insomnia, anxiety, impaired attention, aggression, irritability; thrombocytopenia; myalgia; visual disturbances; pruritus, rash. Pancreatitis, hepatic dysfunction, confusion, psychosis, hallucinations, suicidal ideation, paraesthesia, leucopenia, pancytopenia, and alopecia have also been reported.

Drug interactions
No significant interaction with other drugs has been reported with Levetiracetam.

Contraindications
Levetiracetam is contraindicated in patients with known hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients.

Overdose
The symptoms of overdose that have been observed with overdose of Levetiracetam are somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Citazar®250 tablet: Each film-coated tablet contains Levetiracetam INN 250 mg.
Citazar®500 tablet: Each film-coated tablet contains Levetiracetam INN 500 mg.

Packaging
Citazar®250 tablet: Carton of 20 tablets in Alu-PVC blister
Citazar®500 tablet: Carton of 10 tablets in Alu-PVC blister

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