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Leveron®

Levetiracetam USP

50054

Presentation
Leveron 250mg Tablet: Each tablet contains Levetiracetam USP 250mg.
Leveron 500mg Tablet: Each tablet contains Levetiracetam USP 500mg.
Leveron 100ml Syrup: Each 1ml Syrup contains Levetiracetam 100mg.

Pharmacokinetics:
Levetiracetam is readily absorbed from the gastrointestinal tract with a bioavailability of almost 100%; peak plasma concentrations usually occur within 1.3 hours of oral doses and steady state after 2 days. Plasma protein binding is minimal at less than 10%. Levetiracetam is not extensively metabolised; about 25% of a dose is metabolised by hydroxylation to inactive metabolites. Around 90% of a dose is excreted as unchanged drug and metabolites in the urine. The plasma elimination half-life has been reported to be about 7 hours in adults and children aged 12 years and over; the half-life may be shorter in younger children. Levetiracetam is distributed into breast milk.

Indication
Levetiracetam is indicated –
1. as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy;
2. as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy;
3. as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.

Contra-indications:
Hypersensitivity to Levetiracetam or any of the inactive ingredients.

Side-Effect
Nausea, vomiting, dyspepsia, diarrhoea, abdominal pain, anorexia, weight changes; cough; drowsiness, asthenia, amnesia, ataxia, seizures, dizziness, headache, tremor, hyperkinesia, depression, emotional lability, insomnia, anxiety, impaired attention, aggression, irritability; thrombocytopenia; myalgia; visual disturbances; pruritis, rash; also reported pancreatitis, hepatic dysfunction, confusion, psychosis, hallucinations, suicidal ideation, paraesthesia, leucopenia, pancytopenia and alopecia.

Precautions
Patients should be advised that Levetiracetam may cause dizziness and somnolence. Accordingly, patients should be advised not to drive or operate machinery or engage in other hazardous activities until they have gained sufficient experience on Levetiracetam to gauge whether it adversely affects their performance of these activities. Patients should be advised that Levetiracetam may cause changes in behavior (e.g. aggression, agitation, anger, anxiety, apathy, depression, hostility and irritability) and in rare cases patients may experience psychotic symptoms and/or suicidal ideation.

Pregnancy and Lactation
There are no adequate data from the use of Levetiracetam in pregnant women. Levetiracetam should not be used during pregnancy unless clearly necessary.

Discontinuation of antiepileptic treatments may be harmful to the mother and the foetus.
Levetiracetam is excreted in human breast milk. Therefore, breast-feeding is not recommended.

Dose and Administration
Monotherapy:
Adult 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 250mg twice daily every two weeks depending upon the clinical response. The maximum dose is 150mg twice daily.
Adult and adolescents (12-17 years) weight 50kg or more:
The initial therapeutic dose is 500mg twice daily. The dose can be started on the first day of treatment. Depending upon the clinical response & tolerability, the daily dose can be increased up to 1500mg twice daily. Dose changes can be made in 500mg twice daily increases or decreases every 2 to 4 weeks.

Elderly (65 years and older): Adjustment of the dose is recommended in elderly patients with compromised renal function.

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

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.

Patients with renal and hepatic impairment:
The daily dose must be individualised according to renal function. No dose adjustment is needed in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore a 50% reduction of the daily maintenance dose is recommended when the creatinine clearance is <70ml/min.

Drug Interactions:
Phenytoin: Levetiracetam (3000mg daily) had no effect on the pharmacokinetic disposition of phenytoin in patients with refractory epilepsy. Pharmacokinetics of levetiracetam were also not affected by phenytoin.

Valporate: Levetiracetam (1500mg twicw daily) did not alter the pharmacokinetics of valporate in healthy volunteers. Valporate 500mg twice daily did not modify the rate or extent of levetiracetam absorption or its plasma clearance or urinary excretion.

Potential drug interaction between levetiracetam and other ADEs (carbamazepine, gabapentin, lamotrigine, Phenobarbital, phenytoin, primidone, and valporate) were also assessed by evaluating the serum concentrations of levetiracetam and these AEDs during placebo-controlled clinical studies. These data indicate that levetiracetam does not influence by plasma concentration of other AEDs and that these AEDs do not influence the pharmacokinetics of levetiracetam.

Over dosage: The highest known dose of levetiracetam received in the clinical development program was 6000mg/day. Other than drawsiness, there were no adverse events in the few known cases of overdose in clinical trials. Cases of somnolence, agitation, aggression, depressed level of consciousness, respiratory depression, and coma were observed with of levetiracetam overdoses in post marketing use. If indicated, elimination of unabsorbed drug should be attempted by emesis or gastric lavage; usual precautions should be observed to maintain airway.

Storage Condition: Store at a cool temperature (not exceeding 25°C) and dry place, protected from light.

Commercial Pack:
Leveron 250mg Tablet: 5x6's tablet in alu-alu blister pack.
Leveron 500mg Tablet: 5x4's tablet in alu-alu blister pack.
Leveron 100ml Syrup: leveron syrup 100ml Bottle.

Manufactured by:
synovia
Synovia Pharma PLC., Station Road, Tongi, Gazipur.
A Subsidiary of BEXIMCO PHARMACEUTICALS LTD.

538115

Direction Slip artwork legend

Product Name	:	Leveron
Code number	:	538115
Dimension	:	L 10.5 x W 2.36 inches
Min. size of text	:	7 pt
Used Colors	:	Black C ■ Pantone 186 C ■