Affect lability/mood
28 mg (0.3 ml) twice daily

Starting dose:
450 mg twice daily

Choreoathetosis, dyskinesia, paraesthesia, lethargy, gait disturbance, seizures aggravated

Note:
Levetiracetam has been administered to more than 3,000 subjects and patients. One thousand and twenty three (1,023) patients with epilepsy participated in controlled clinical studies.

The initial therapeutic dose is 10 mg/kg twice daily.

Dosage recommendations for infants less than 6 months:

Maximum dose:
10 to 20 mg/kg (0.10 to 0.20 ml/kg) twice daily

Maximum dose (dose for oral solution):
10 to 20 mg/kg (0.10 to 0.20 ml/kg) twice daily

Hepatic impairment

- In the treatment of partial onset of seizures in adults with epilepsy.

As adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in adults, children and infants from 1 month of age with epilepsy.

The cumulative urinary excretion of levetiracetam and its primary metabolite accounted for 66% and 24% of the dose, respectively during the first 48 hours. The renal clearance of levetiracetam was up to 1.4 ml/min/kg in patients with normal renal function. In patients with impaired renal function, the clearance was reduced by about 50%.

In subjects with mild (Child-Pugh A) to moderate (Child-Pugh B) hepatic impairment, the pharmacokinetics of levetiracetam were unchanged. In subjects with severe hepatic impairment (Child-Pugh C), the apparent clearance was faster (1.5 ml/min/kg) than for adults (0.96 ml/min/kg).

Infants and children (1 month to 4 years) Following single dose administration (20 mg/kg) of a 100 mg/ml oral solution to epileptic children (1 month to 4 years), levetiracetam was rapidly absorbed, with elimination half-life of about 1 hour. The levetiracetam concentration-time profile showed significant inter-individual variability.

For young adolescents, children and infants, using the following formula (Schwartz formula):

\[ \text{Dose} = \frac{\text{Ideal body weight} \times \text{Recommended dose in adults}}{1.73 \times \text{CLcr}} \]

where CLcr is the creatinine clearance, expressed in ml/min.

The dose should be adjusted weekly or every two to four weeks. The lowest effective dose should be used.

Psychiatric reactions and changes in behavior

levetiracetam should be monitored for psychiatric signs and symptoms.

Psychiatric reactions and changes in behavior

In subjects with normal renal and hepatic function, the pharmacokinetics of levetiracetam and its primary metabolite, ucb L057, were similar to those observed in subjects with normal renal function. In subjects with severe hepatic impairment (Child-Pugh C), the apparent clearance was faster (1.5 ml/min/kg) than for adults (0.96 ml/min/kg).

Metabolism and nutrition disorders

Levetiracetam is a highly soluble and permeable compound. The pharmacokinetic profile is linear and time-independent with low intra- and inter-subject variability. There is no modification of the pharmacokinetics of levetiracetam observed in the elderly population.

Eye disorders

No serious adverse reactions were experienced in patients in the levetiracetam or placebo group. During the long-term follow-up study period, patients received up to 4 years of therapy.

In subjects with normal renal and hepatic function, the pharmacokinetics of levetiracetam and its primary metabolite, ucb L057, were similar to those observed in subjects with normal renal function. In subjects with severe hepatic impairment (Child-Pugh C), the apparent clearance was faster (1.5 ml/min/kg) than for adults (0.96 ml/min/kg).

In vitro, levetiracetam showed no stimulation or inhibition of human cytochrome P450 isoforms.

Anticonvulsants

The systemic exposure of levetiracetam was increased when levetiracetam was coadministered with lamotrigine, carbamazepine, phenytoin, topiramate, valproate, gabapentin, ethosuximide, primidone, vigabatrin, and phenobarbital. In subjects with hepatic impairment (Child-Pugh B), the pharmacokinetics of levetiracetam were unchanged. In subjects with severe hepatic impairment (Child-Pugh C), the apparent clearance was faster (1.5 ml/min/kg) than for adults (0.96 ml/min/kg).

In vitro, levetiracetam showed no stimulation or inhibition of human cytochrome P450 isoforms.