For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory xxxxxxxx-8883

VALPARIN-200 ALKALETS

(Sodium Valproate Enteric Coated Tablets B.P., 200 mg)

DESCRIPTION :

Valparin alkalets are enteric coated sodium valproate tablets available in strength of 200 mg. It is indicated in various types of convulsive disorders as single drug therapy or used in combination with other antiepileptic agents.

CLINICAL PHARMACOLOGY :

Valparin alkalets dissolves in the alkaline pH of intestine, due to which absorption of the drug is delayed by 1 hour as compared to ordinary or conventional valproate tablets. However, the active drug is uniformly absorbed. Peak serum levels of valproate occur in 3 to 4 hours. Bio-availability of Valparin alkalets is similar to that of conventional sodium valproate tablet. The incidence of side effects due to irritation of gastrointestinal tract is considerably reduced. The plasma protein binding is 90% and biotransformation is by inactivation in liver.

INDICATIONS :

Valparin alkalets is indicated in management of various types of seizures such as absence seizures, infantile spasm, myoclonic seizures, generalized tonic clonic seizures, intractable epilepsy and febrile seizures.

CONTRAINDICATIONS :

Pregnancy, impaired liver function and hypersensitivity to valproate.

PRECAUTIONS :

Valparin alkalets should be swallowed and not chewed by the patient. Valproate is excreted in the breast milk in concentrations of 1 to 10% of serum concentrations. Cautions should be exercised when Valparin alkalets is administered to a nursing women.

ADVERSE REACTIONS :

The gastrointestinal side effects such as nausea, vomiting and indigestion are less frequent with Valparin alkalets. Sedation, tremors, ataxia, headache, nystagmus, diplopia, dysarthria, dizziness and incoordination have also been reported. Skin rash and transient increase in hair loss have also been reported. Valparin rarely causes thrombocytopenia and liver injury.

DRUG INTERACTIONS :

Like many other drugs, Valparin alkalets may potentiate the effects of neuroleptics, monoamine oxidase inhibitors and other antidepressants.The enzyme inducing effect of vaparin alkalets is appreciably less than that of certain other anticonvulsants and loss of efficacy of oral contraceptive agents does not appear to be a problem.

Caution is recommended when administering anticoagulants and other products which have anticoagulant properties (e.g.warfarin and salicylates). Valparin alkalets decreases protein binding of warfarin but this may not lead to clinically significant effects. Phenytoin levels may be affected by Valparin alkalets, and these should be monitored, particularly the free form which may increase following an initial decrease in total levels.

Valparin alkalets may inhibit the metabolism of lamotrigine. Dosage of Valparin alkalets may require adjustment when used in combination with other anticonvulsants. There is evidence that cimetidine, but not ranitidine may prolong the half life and reduce clearance of Valparin alkalets.

The absorption of Valparin alkalets may be decreased in the presence of cholestyramine.

DOSAGE AND ADMINISTRATION :

Daily dosage requirements vary according to age and body weight.

Adults : Dosage should start at 600 mg daily increasing by 200 mg at three days intervals until control is achieved. This is generally within the dosage range 1000mg to 2000mg per day i.e. 20-30 mg/kg body weight. Where adequate control is not achieved within this range the dose may be further increased to 50 mg/kg body wt.

Children over 20kg : Initial dosage should be 400mg/day (irrespective of weight) with spaced increases until control is achieved. This is usually within the range 20-30 mg/kg body weight per day. Where adequate control is not achieved within this range the daily dose may be increased to 35mg/kg body weight.

OVERDOSAGE :

Cases of accidental and suicidal overdosage have been reported. At plasma concentration of up to 5 to 6 times the maximum therapeutic levels, there are unlikely to be any symptoms other thana nausea, vomiting and dizziness. In massive overdose, i.e. with plasma concentrations 10 to 20 times maximum therapeutic levels there may be serious CNS depression and respiration may be impaired. The symptoms may however be variable and seizures have been reported in the presence of very high plasma levels. A number of deaths have occurred following large overdoses. Full recovery is usual following treatment including induced vomiting, gastric lavage, assisted ventilation and other supportive measures.

PRESENTATION :

Valparin alkalets are supplied in strip of 10 tablets, each enteric coated tablet containing sodium valproate 200 mg.

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Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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