Prescribing Information
For the use of a Registered Medical Practitioner, or Hospital, or Laboratory only.

VALPROL CR-300

(Controlled release tablets of Sodium Valproate & Valproic Acid)

Composition

Each film coated controlled release tablet contains:
Sodium Valproate BP 200 mg
Valproic Acid USP 87 mg
(Both together corresponds to Sodium valproate 300 mg)

Description

The product is a combination of two drugs sodium valproate and valproic acid in controlled release form. Sodium valproate and valproic acid are antiepileptic agents and used in the treatment of various forms of epilepsy. The sustained release product improves patient compliance.

Clinical pharmacology
Mode of Action

Sodium Valproate produces its effect by increasing the levels of GABA (gamma aminobutyric acid) in the brain and increases the response to GABA in the postsynaptic neurons. Additionally, sodium valproate affects potassium flow across the neurons. The result of these effects is inhibition of initiation as well as spread of epileptic activity in the neurons.

Pharmacodynamics

Valproate produces its antiepileptic effects in several different types of epilepsy. It is therefore sometimes called the broad-spectrum anti-epileptic drug. It has no significant hypnosedative effects. It does not have undesirable effect on blood pressure, heart rate, kidney functions & body temperature.

Pharmacokinetics

Absorption is rapid and complete. Peak plasma concentrations are achieved between 2-8 hours after oral administration of controlled release tablets. Protein binding is between 80 -95% and elimination half-life is 8-22 hours. The effective therapeutic plasma concentration of valproic acid is between 50 - 100 mcg/ml. The pharmacological and therapeutic effects of controlled release preparation of this drug may not always clearly co-related with plasma concentrations. The controlled release tablets reduce fluctuations in peak and trough concentration. Therefore uniform antiepileptic protection is provided on a 24 hourly basis. Volume of distribution is 0.2 ltrs/kg bodyweight. It is metabolised in liver and is excreted by the kidney. There is no pre-systematic metabolism. The controlled release formulation reduces possibility of fluctuations in plasma concentrations as compared to conventional formulations.

Indications

The controlled release preparation is indicated as monotherapy or adjunctive therapy in the treatment of generalised, partial or other epilepsy. Also indicated in bipolar affective disorders.

Dosage and administration

Adults : The usual dose of the product is between 1000 mg and 2000 mg/day but may be increased to 2500 mg/day. The medicine may be given in one or two separate doses.

Children over 20 kg. : The usual dose of the product is based on the child's weight. The usual dose is between 20 and 30 mg/kg body weight but may be increased to 35 mg/kg body weight. This quantity may be given in one dose or can be divided and given in two separate doses e.g. half in the morning and half in the evening. This product is not suitable for use in children under 20kg.

Dosage should be reduced in elderly and patients with renal impairment.

Valprol CR_PIL(8608945)-Front
Size : 210 x 140 (mm)
Folding Size 140 x 26.5 (mm)
Pantone Black
Dt. : 05/08/2015

Contraindications, Precautions & Warnings

This controlled release preparation is contraindicated in patients with hypersensitivity to it. It is also contraindicated in patients with active liver disease, family history to severe hepatic dysfunction, particularly drug related. Caution should be exercised in patients with hepatic disease, liver function tests should be performed prior to therapy and at frequent intervals, especially during the first six months. Patients on multiple anticonvulsants, children, those with congenital metabolic disorders, those with severe seizure disorders accompanied by mental retardation, when this controlled release preparation is to be used in these groups of patients, it should be used with extreme caution.

Use in pregnancy & lactation

This controlled release preparation should be used during pregnancy only if potential benefits outweigh the potential risk to the foetus. It should not be used during lactation.

Drug interactions

The controlled release preparation potentiate the effects of neuroleptics, monoamine oxidase inhibitors and other antidepressants. Phenytoin levels may be affected by valproate and these should be monitored, particularly the free form which may increase following an initial decrease in total levels. Valproate may inhibits the metabolism of lamotrigine. Cimetidine prolongs the half-life and reduce clearance of valproate. Cholestyramine decreases absorption of valproate. The enzyme inducing effect of valproate is appreciably less than that of certain anticonvulsants.

Side effects

This product is very well tolerated. This controlled release preparation causes mild to moderate side effects. It causes malaise, weakness, jaundice, abdominal pain, anorexia, drowsiness, hyperammonaemia, pancreatitis, thrombocytopeania, ataxia, tremors, weight gain, skin rashes, transient hair loss etc.

Overdosage

Cases of accidental and suicidal overdosage have been reported. In massive overdosage, 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. Recovery is possible after the treatment which may include, induced vomiting, gastric lavage, assisted ventilation, and other supportive measures.

Storage

Store below 25^{0}C, protected from light & moisture.

Presentation

Available in aluminium blisters of 10 tablets.

Manufactured by :
INTAS
INTAS LIFESCIENCES PRIVATE LIMITED
Selaqui, Dehradun-248 197. INDIA
80 12814 1 8608945

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