Only for the use of Medical Professionals

Sodival®

Sodium Valproate

Description

Sodival® is a preparation of Sodium Valproate which is an antiepileptic agent. The mode of action of Sodium Valproate is potentiation of the inhibitory action of gamma amino-butyric acid (GABA) through an action on increased synthesis or decreased metabolism of GABA.

Indication and usage

Sodival® is indicated for the treatment of all forms of epilepsy.

Dosage and administration

Adults

Dosage should start at 600mg in 2 divided doses daily increasing by 200mg at three-day intervals to a maximum 2500mg per day in divided doses until control is achieved.
Usual maintenance dose: 1-2g per day (20-30mg/kg/day).

Children under 12 years body-weight over 20 kg

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

Children body-weight upto 20 kg

Initially 20mg/kg daily in divided doses; in severe cases this may be increased upto 40mg by monitoring patient plasma valproic acid level. But above 40mg/kg/day clinical chemistry and haematological parameters should be monitored.

Use in the elderly

Although the pharmacokinetics of Sodival® are modified in the elderly, they have limited clinical significance and dosage should be determined by seizure control. The volume of distribution is increased in the elderly and because of decreased binding to serum albumin, the proportion of free drug is increased. This will affect the clinical interpretation of plasma valproic acid levels.

Renally impaired patients

In patients with renal insufficiency, it may be necessary to decrease the dosage and dosage should be adjusted according to free serum-valproic acid concentration.

Use in pregnancy and lactation

Increased risk of congenital malformations and developmental delay if used in the first trimester. Sodium Valproate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Excretion in breast milk is low & breast-feeding by a mother taking Sodium Valproate probably causes no risk to the child.

Precautions

Monitor liver function before therapy and during first 6 months especially in patients most at risk; measure full blood count and ensure no undue potential for bleeding before starting and before surgery; systemic lupus erythematosus; false-positive urine tests for ketones;

avoid abrupt withdrawal; consider vitamin D supplementation in patients that are immobilised for long periods or who have inadequate sun exposure or dietary intake of calcium.

Side effects
Common: nausea, gastric irritation, diarrhea; weight gain; hyperammonaemia, thrombocytopenia; transient hair loss (regrowth may be curly); Less frequent: increased alertness, aggression, hyperactivity, behavioural disturbances, ataxia, tremor, and vasculitis; Rare: hepatic dysfunction, lethargy, drowsiness, confusion, stupor, hallucinations, menstrual disturbances, anaemia, leucopenia, pancytopenia, hearing loss, and rash; Very Rare: pancreatitis, peripheral oedema, increase in bleeding time, extrapyramidal symptoms, dementia, encephalopathy, coma, gynaecomastia, Fanconi's syndrome, hirsutism, acne, enuresis, hyponatraemia, toxic epidermal necrolysis, and Stevens-Johnson syndrome; suicidal ideation; reduced bone mineral density.

Drug interactions
Sodium Valproate appears to act as a non specific inhibitor of drug metabolism. Drugs to which it interacts most significantly are Phenobarbital, Phenytoin, Warfarin, Salicylates.

Contraindications
Sodium valproate is contraindicated in patients with severe hepatic dysfunction, porphyria and known hypersensitivity to the active substance or to any of the excipients.

Overdose
Cases of accidental and deliberate Sodium Valproate overdosage have been reported. At plasma concentrations of up to 5 to 6 times the maximum therapeutic levels, there are unlikely to be any symptoms other than nausea, vomiting and dizziness.
Management of overdose should be symptomatic, including cardio-respiratory monitoring. Gastric lavage may be useful up to 10 to 12 hours following ingestion.

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

Presentation
Sodival® tablet: Each enteric coated tablet contains Sodium Valproate BP 200mg
Sodival® syrup: Each 5ml contains Sodium Valproate BP 200mg

Package quantities
Sodival® tablet: Carton of 50 tablets in blister pack
Sodival® syrup: Bottle of 100ml

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