

Sodium valproate syrup



100 ml of syrup contains:

Sodium valproate.....5.764 g

Excipients are: methylparaben, propylparaben, sucrose, sorbitol 70%, glycerol and artificial cherry flavor.

A small dosing spoon contains: 100 mg sodium valproate

A large dosing spoon contains: 200 mg sodium valproate

Sodium valproate syrup :

Each 5 ml of syrup contains Sodium Valproate BP 200 mg.

Description

Sodium Valproate, the active ingredient of Sodium valproate is endowed with anti-epileptic activity against a variety of seizures. The mechanism by which Sodium Valproate exerts its anti-epileptic effects has not been established. However, it has been suggested that its activity is related to increased brain levels of gamma-aminobutyric acid (GABA).

Indications

Sodium valproate is indicated for the treatment of all types of epilepsy, e.g. Partial seizures, Absence seizures (petit mal), Generalized tonic-clonic seizures (grand mal), Myoclonic seizures, Atonic seizures, Mixed seizures that include absence attack, Prophylaxis of febrile convulsion, Prophylaxis of post-traumatic epilepsy.

Dosage and Administration

Age group Dosage & Administration

Adults Initially 600 mg daily given in 2 divided doses, preferably after food, increasing by 200 mg/day at 3-day intervals to a maximum of 2.5 g daily in divided doses until control of seizure is achieved.

Usual maintenance dose is 1-2 g daily (20-30 mg/kg daily).

Children Initially 20 mg/kg daily in divided doses, may be increased

(up to 20 kg) provided plasma concentrations monitored (above 40 mg/kg daily also monitor clinical chemistry and hematological parameters).

Children Initially 400 mg daily in divided doses increased until control

(Over 20 kg) (usually in the range of 20-30 mg/kg daily); Maximum 35 mg/kg daily.

Side effects

The most common side effects are anorexia, nausea and vomiting. However, these side effects are minimized with the use of enteric coated tablets. Effects on the CNS include sedation, ataxia and tremor. These symptoms occur infrequently and usually respond to a decrease in doses. Rash, alopecia and stimulation of appetite have been observed occasionally. Sodium Valproate has several effects on hepatic function of which elevation of liver enzymes in plasma is observed in up to 40% of patients and often occurs asymptotically during the first few months of therapy. Rarely a fulminate hepatitis that may be fatal may develop. Children below 2 years of age with other medical conditions and those being treated with multiple antiepileptic agents are specially prone to suffer from hepatic injury, acute pancreatitis and hyperammonemia have also been frequently associated with the use of Sodium Valproate.

Contraindications

Sodium Valproate is contraindicated to patients who have known hypersensitivity to the drug and liver dysfunction. Care should be exercised when prescribing Sodium Valproate in women of child bearing age.





Precautions

Liver functions should be monitored before therapy and during first 6 months especially in patients most at risk, No undue potential for bleeding before starting and before major surgery must be ensured, Care should be taken in renal impairment, pregnancy, breast-feeding and systemic lupus erythematosus. Sodium Valproate is partially eliminated in the urine as a ketone metabolite, which may lead to a false interpretation of the urine ketone test. Sudden withdrawal of therapy should be avoided.

Use in Pregnancy & Lactation

Sodium Valproate crosses the placenta and in humans, exposure to valproate in the first trimester has been associated with neural tube defects such as anencephaly and spina bifida in newborn.

Pregnant women treated with Sodium valproate should be offered to estimate serum a-fetoprotein. Sodium valproate is excreted in breast milk. However, breast-feeding by a mother taking Sodium valproate probably causes no risk to the child.

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, Aspirin etc.

Commercial pack

Sodium valproate syrup : Bottle containing 100 ml of Sodium Valproate syrup.

For Information about Generic Medicines : genericmedicines@tajpharma.com

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.



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