Convules® Syrup

Sodium Valproate

Description: Sodium valproate, the active ingredient, is endowed with anti-epileptic activity against a variety of seizures.

Mechanism of action: The mechanism of action of **Convules® Syrup** has not been fully established. Its anticonvulsant effect is attributed to the blockage of voltage depended Na^+ channels and increased brain levels of gamma-aminobutyric acid (GABA). Convules Syrup raises cerebral and cerebellar levels of the inhibitory synaptic transmitter, GABA, possibly by inhibiting GABA degradative enzymes such as GABA transaminase and/or succinic semialdehyde dehydrogenase and/or by inhibiting the reuptake of GABA by neural cells.

Composition: Convules® Syrup: Each 5 ml contains Sodium Valproate BP 200 mg.

Indications: *Epilepsy*: 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 and specific syndromes (west, Lennox-Gastaut).

Mania: For the treatment of manic episodes of bipolar disorder.

Other: As an alternative treatment of febrile convulsion and migraine prophylaxis.

Dosage & administration: Dosage requirements vary according to age and body weight and should be adjusted individually to achieve adequate seizure control. The daily dosage should be given in 1 - 2 single doses.

Epilepsy	
Adults	Should be started with 600 mg daily increasing by 200 mg at three days intervals until controlled is achieved. This is generally within the dosage range 1000-2000 mg per day , i.e., 20-30 mg per kg body weight. If adequate control is not achieved with in the range the dose may be further increased to 2500 mg per day.
Children > 20 kg	Initially dosage 400 mg daily with space increases until control is achieved; this is usually within the range 20-30 mg/ kg body weight per day.
Children < 20 kg	20 mg /kg body weight per day; in sever case this may be increased but only in patients in whom plasma valproic acid levels can be monitored. Above 40 mg/kg body weight per day, clinical chemistry and hematological parameters should be monitored.
Mania	Should be started with 600 mg daily increasing by 200 mg at three days intervals until controlled is achieved This is generally within the dosage range 1000-2000 mg per day , i.e., 20-30 mg per kg body weight. If adequate control is not achieved with in the range the dose may be further increased to 2500 mg per day.
Febrile convulsion	20-30 mg/kg body weight per day
Bipolar disorder	Initially 20 mg/kg body weight per day in 2-3 divided doses; adjust dosage in 3-5 days.
Prophylaxis of migraine	300 mg twice daily

Contraindication: 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.

Side effects: The most common side effects are anorexia, nausea and vomiting. 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 asymptomatically during the first few months of therapy. Children below 2 years of age with other medical conditions and those being treated with multiple antiepileptic agents are especially prone to suffer from hepatic injury; acute pancreatitis and hyperammonemia have also been frequently associated with the use of Sodium valproate.

Use in pregnancy and 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. Excretion of Valproate in breast milk is very low and the breast-fed neonates have no experienced clinical effects. There appears to be no contraindication to breast feeding by patients on valproate.

Precaution: 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.

Drug Interaction: 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.

Over dosage: *Symptoms*: Symptoms of over dosage may include serious CNS depression and impairment of respiration. Signs of an acute over massive overdose usually include coma, with muscular hypotonia, hyporeflexia and miosis, impaired respiratory functions and metabolic acidosis. Symptoms may however be variable and seizures have been reported in the presence of very high plasma levels. Intracranial hypertension related to cerebral edema has been reported.
Treatment: Establish airway and breathing and evaluate circulatory status Assisted mechanical ventilation may be required in cases of respiratory depression. Activated charcoal may reduce the absorption of the medicine if given with in one or two hours after ingestion. Haemodialysis and haemoperfusion have been successfully removed the drug significantly. Intravenous naloxone has been used sometimes in association with activated charcoal given orally. Particular attention should be given to the maintenance of an adequate urinary output. Hepatic and pancreatic function should be monitored.

Storage: Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging: Convules® Syrup: Each bottle contains 100 ml syrup.

Opsonin Pharma
Ideas for healthcare

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