

SODIUM VALPROATE

xxxxxxx-5343

VALPARIN-200

200 mg / 5 mL Syrup
ANTICONVULSANT

FORMULATION:

Each 5mL contains:
Sodium Valproate 200 mg

PHARMACOLOGY:

Sodium Valproate increases the level of GABA in the brain by inhibiting succinic semialdehyde dehydrogenase and to a lesser extent glutamate transaminase. It is quickly absorbed from GIT. The plasma binding is 90% and biotransformation is by inactivation in liver. Serum half-life is about 4-6 hours. Single dose is excreted within 24 hours, about 70% in the urine.

INDICATIONS:

For the treatment of generalized epilepsy particularly with absence, myoclonic, tonic-clonic, atonic and mixed patterns of seizures and partial epilepsy particularly with simple or complex, secondary, generalized, specific syndromes (Lennox Gastaut).

DOSAGE AND ADMINISTRATION:

In Children - 20-50 mg/kg body weight in divided doses

In Adults - In adults who cannot swallow tablets, is initially given as 600 mg a day in divided doses. This may be increased by 200 mg a day at an interval of 3 days, up to 1000-2000 mg daily until desired effect is achieved.
Or as prescribed by the physician.

CONTRAINDICATIONS:

Pregnancy, impaired liver functions and hypersensitivity to Sodium Valproate.

PRECAUTIONS:

Liver functions need to be monitored in early phase of treatment and during dose treatment. Caution should be exercised when Sodium Valproate is administered to nursing women. Use during pregnancy only if absolutely essential.

This product contains FD&C Yellow No. 5 Tartrazine) which may cause allergic type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (Tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE EFFECTS:

The gastrointestinal adverse effects such as nausea, vomiting and indigestion are less frequent with Sodium Valproate. Sedation, tremors, ataxia, headache, nystagmus, diplopia, dysarthria, dizziness and in-coordination have also been reported. Skin rash and transient increase in hair loss have also been reported. Sodium Valproate rarely causes thrombocytopenia and liver damage, acute pancreatitis.

DRUG INTERACTION:

Sodium Valproate may potentiate the effect of MAOI's and other antidepressants. Caution is recommended when administering anticoagulants. Sodium Valproate is eliminated mainly through kidneys, partly in the form of ketone bodies; this may give false positives in urine testing of diabetics.

OVERDOSAGE:

Massive overdosage (10-20 times maximum therapeutic levels) cause serious CNS and respiratory depression. Full recovery is there, usually following treatment including induced vomiting, gastric lavage, assisted ventilation and other supportive measures.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C. Protected from light.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:

Sodium Valproate (Valparin-200) 200 mg /5 mL Syrup - In Amber Glass Bottle - 100mL with measuring cup in a box.



Manufactured by :

ELYSIUM PHARMACEUTICALS LTD.

Plot No 1175, At & Post: Dabhasa Tal: Padra,

Dist: Vadodara, Gujarat 391 440, INDIA.

For :

TORRENT PHARMACEUTICALS LTD.

Indrad-382 721, Dist. Mehsana, INDIA.

Imported and Distributed by :

TORRENT PHARMA PHILIPPINES INC.

Unit 601, 6/F, ITC Building, 337 Sen. Gil Puyat Avenue,

Makati City, PHILIPPINES