TORVATE

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for Torvate (Controlled Release Tablets of Sodium Valproate I.P. 200,300,500,750,1000mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Valproate belongs to pharmacotherapeutic group antiepileptics. The most likely mode of action for Sodium valproate is potentiation of the inhibitory action of gamma amino-butyric acid (GABA) through an action on the further synthesis or further metabolism of GABA. **INDICATION:** It is indicated in the management of simple and complex absence seizures and generalized tonic-clonic seizures (grand mal).

DOSAGE AND ADMINISTRATION: Sodium valproate tablets may be given twice daily. Tablets should be swallowed whole and not crushed or chewed. In adults: Dosage should start at 600mg daily. The dose is generally within the dosage range 1000mg to 2000mg per day, i.e. 20-30mg/kg/day body weight. Children over 20kg: Initial dosage should be 400mg/day. Children under 20kg: 20mg/kg of body weight per day. In patients with renal insufficiency: It may be necessary to decrease the dosage.

CONTRAINDICATION: It is contraindicated in patients of acute liver disease, personal or family history of severe hepatic dysfunction especially drug related, Hypersensitivity to sodium valproate, porphyria, in patients known to have mitochondrial disorders.

WARNINGS & PRECAUTIONS: Drug discontinuation should be done gradually and under medical supervision. Severe liver damage, including hepatic failure may occur. After the age of 3 years, the incidence of occurrence is significantly reduced and progressively decreases with age. The concomitant use of salicylates should be avoided in children. The use of valproate may associate with Pancreatitis. Young children are at particular risk; it decreases with increasing age. It should not be used in female children, in female adolescents, in women of childbearing potential and pregnant women unless alternative treatments are ineffective. It may cause suicidal ideation and behavior. The concomitant use of valproate and carbapenem agents and alcohol is not recommended. It may cause weight gain. The dosage should be managed and monitored for Haematological disorders, renal insufficiency, systemic lupus erythromatosus and hyperammonemia.

DRUG INTERACTIONS: Valproate interacts with antipsychotics, mao inhibitors, antidepressants and benzodiazepines**,** lithium, phenobarbital, primidone, phenytoin, carbamazepine, lamotrigine, felbamate, zidovudine, vitamin k-dependent anticoagulants and temozolomide.

ADVERSE REACTIONS: Liver injury, nausea, gastralgia, diarrhea, tremor, extrapyramidal disorder, confusional state, aggression, agitation, hyponatraemia, syndrome of inappropriate secretion of adh, anaemia, thrombocytopenia, transient and or dose related alopecia, dysmenorrhea, haemorrhage, deafness, enuresis, bone mineral density decreased, weight increased, anaemia, thrombocytopenia, pancytopenia, leucopenia, hypersensitivity, transient and or dose related alopecia (hair loss), angioedema, rash, toxic epidermal necrolysis, stevens-johnson syndrome, erythema multiforme, drug rash with eosinophilia and systemic symptoms (DRESS) syndrome, dysmenorrhea, amenorrhea, haemorrhage, deafness and weight increased.

MARKETED BY:

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(Additional information is available on request)