TORVATE CHRONO

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

Abbreviated Prescribing information for **TORVATE CHRONO** [Sodium valproate and valproic acid I. P. 133.5 mg valproic Acid I.P. 58 mg (Both together corresponds to sodium valproate and valproic acid **200 mg**), sodium valproate and valproic acid I.P. 200 mg valproic Acid I. P. 87 mg (Both together corresponds to sodium valproate and valproic acid **300 mg**), Sodium valproate and valproic acid I.P. 333 mg valproic Acid I.P. 145 mg (Both together corresponds to Sodium valproate and valproic acid **500 mg**)] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Sodium valproate and valproic acid are anticonvulsants. The most likely mode of action for Sodium valproate and valproic acid 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: In the treatment of generalized epilepsy, particularly with patterns of absence, myoclonic, tonic-clonic, atonic, and mixed seizures and in the treatment of partial epilepsy: Simple or complex seizures, secondary generalized seizures, specific syndromes (West, Lennox - Gastaut) and treatment and prevention of mania associated with bipolar disorder.

DOSAGE AND ADMINISTRATION: Daily dosage requirements vary according to age and body weight. Sodium valproate and valproic acid tablets may be given twice daily. Tablets should be swallowed whole and not crushed or chewed.

CONTRAINDICATION: Contraindicated in patients with active liver disease, personal or family history of severe hepatic dysfunction, especially drug related, hypersensitivity to sodium valproate, porphyria and mitochondrial disorders.

WARNINGS & PRECAUTIONS: Use cautiously and stop the Torvate Chrono in patients with liver dysfunction, pancreatitis, female children/female adolescents/women of childbearing potential or pregnancy, suicidal ideation and behavior, with carbapenem agents, known or suspected mitochondrial disease, haematological disturbance, renal insufficiency, systemic lupus erythematosus, hyperammonaemia, weight gain, diabetic patients and with alcohol.

DRUG INTERACTIONS: *Antipsychoticss, MAO inhibitors, antidepressants and benzodiazepines,* lithium, phenobarbital, primidone, phenytoin, carbamazepine, lamotrigine, felbamate, zidovudine, vitamin k-dependent anticoagulants, temozolomide mefloquine, chloroquine, highly protein bound agents (e.g. aspirin), cimetidine or erythromycin, carbapenem antibiotics such as imipenem, panipenem and meropenem, topiramate and oestroprogestative agents.

ADVERSE REACTIONS: Liver injury, nausea, gastralgia, diarrhea, tremor, extrapyramidal disorder, stupor, somnolence, convulsion, memory impairment, headache, nystagmus, confusional state, aggression, agitation, disturbance in attention, hyponatraemia, anaemia, thrombocytopenia, hypersensitivity, transient and or dose related alopecia (hair loss), dysmenorrhea, haemorrhage, deafness and weight increased.

MARKETED BY:

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IN/ TORVATE CHRONO 200,300,500mg/Oct-2015/01/ABPI

(Additional information is available on request)