TREND XR

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

Abbreviated Prescribing information for **TREND XR** [Divalproex sodium 250mg, 500mg, 750mg and 1000mg prolonged release tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Divalproex sodium dissociates to the valproate ion in the gastrointestinal tract. Its activity in epilepsy is related to increased brain concentrations of gamma-aminobutyric acid (GABA).

INDICATION: **Epilepsy:** indicated as monotherapy and adjunctive therapy in the treatment of adults and children 10 years of age or older with complex partial seizures that occur either isolation or in association with other types of seizures. Also indicated for use as sole and adjunctive therapy in the treatment of simple and complex absence seizures in adults and children 10 years of age or older, and adjunctively in adults and children 10 years of age or older with multiple seizure types that include absence seizures. **Mania:** indicated for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. **Migraine:** indicated for prophylaxis of migraine in adults.

DOSAGE AND ADMINISTRATION: **Epilepsy:** Complex partial seizures for adult patients and children 10 years of age or older and simple and complex absence seizures for adult patients and children 10 years of age or older: 10 to 15 mg/kg/day. **Migraine:** the recommended starting dose is 500 mg once daily for 1 week, thereafter increasing to 1000 mg once daily. **Mania:** the recommended initial dose is 25 mg/kg/day given once daily.

CONTRAINDICATION: Contraindicated in patients with hepatic disease or significant hepatic dysfunction, have mitochondrial disorders, hypersensitivity, urea cycle disorders and prophylaxis of migraine headaches in pregnant women.

WARNINGS & PRECAUTIONS: Use cautiously and stop the divalproex sodium in patient with hepatotoxicity, known or suspected mitochondrial disease, birth defects, decreased iq following in utero exposure, use in women of childbearing potential, pancreatitis, urea cycle disorders, suicidal behavior and ideation, bleeding and other hematopoietic disorders, hyperammonemia, encephalopathy associated with concomitant topiramate, hypothermia, drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity reactions, interaction with carbapenem antibiotics and somnolence in the elderly. Monitoring drug plasma concentration as well as effect on ketone and thyroid function tests and on HIV and CMV viruses replication.

DRUG INTERACTIONS: Phenytoin, carbamazepine, and phenobarbital (or primidone), antidepressants, aspirin, felbamate, carbapenems, rifampin, alcohol, p450 isozymes (epoxide hydrase, and glucuronyltransferases), tolbutamide, amitriptyline/nortriptyline, carbamazepine, clonazepam, diazepam, ethosuximide, lamotrigine, phenobarbital, phenytoin, topiramate and warfarin.

ADVERSE REACTIONS: Nausea, somnolence, dizziness, vomiting, asthenia, abdominal pain, dyspepsia, rash, headache, asthenia, fever, abdominal pain, diarrhea, anorexia, dyspepsia, constipation, somnolence, tremor, dizziness, diplopia, amblyopia/blurred vision, ataxia, nystagmus, emotional lability, thinking abnormal, amnesia, flu syndrome, infection, bronchitis rhinitis, alopecia, weight loss,

thrombocytopenia, ecchymosis, peripheral edema, pharyngitis, dyspnea, alopecia, amblyopia/blurred vision and tinnitus.

MARKETED BY:

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IN/TREND XR/250,500,750,1000mg/Mar-2015/01/ABPI
(Additional information is available on request)