

## TREND SPRINKLE

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

Abbreviated Prescribing information for **TREND SPRINKLE** [Divalproex sodium 125mg and 250mg sprinkle capsules] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://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:** As monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with other types of seizure. **DOSAGE AND ADMINISTRATION: Epilepsy: Complex Partial Seizures:** for adults and children 10 years of age or older. *Monotherapy (Initial Therapy) and Conversion to Monotherapy and Adjunctive Therapy:* Patients should initiate therapy at 10 to 15 mg/kg/day. The dosage may be increased by 5 to 10 mg/kg/week to achieve optimal clinical response. *Simple and Complex Absence Seizures:* recommended initial dose is 15 mg/kg/day, increasing at one week intervals by 5 to 10 mg/kg/day until seizures are controlled or side effects preclude further increases. This medication may be swallowed whole or may be administered by carefully opening the Capsule and sprinkling the entire contents on a small amount of soft food (Example: honey, pineapple juice, orange juice, milk, milk shake, curd). This drug/food mixture should be swallowed immediately and not chewed. It should not be stored for future use. **CONTRAINDICATION:** Contraindicated in patients with hepatic disease or significant hepatic dysfunction, have mitochondrial disorders, hypersensitivity and urea cycle disorders. **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 hydase, 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 SPRINKLE 125,250mg/Oct-2015/01/Abpi**

(Additional information is available on request)