CLONOTRIL

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

Abbreviated Prescribing information for CLONOTRIL (Clonazepam 0.25mg, 0.5mg, 1mg, 2mg Dispersible Tablet) [Please refer the complete prescribing information available at www.torrentpharma.com].

PHARMACOLOGICAL PROPERTIES: Clonazepam exhibits pharmacological properties which are common to benzodiazepines and include anticonvulsive, sedative, muscle relaxing and anxiolytic effects. **INDICATIONS:** All clinical forms of epileptic disease and seizures in infants, children and adults, especially absence seizures (petit mal) including atypical absence; primary or secondarily generalised tonic-clonic (grand mal), tonic or clonic seizures; partial (focal) seizures with elementary or complex symptomatology; various forms of myoclonic seizures, myoclonus and associated abnormal movements. **DOSAGE AND ADMINISTRATION:** Adult: *Initial*- should not exceed 1mg/day. *Maintenance*- 4-8mg/day. Infants and children: Initial dosage should not exceed 0.25mg/day for infants and small children (1 to 5 years) and 0.5mg/day for older children. *Maintenance dosage:* School children (5 to 12 years) 3 to 6mg, Small children (1 to 5 years) 1 to 3mg, Infants (0 to 1 year) 0.5 to 1mg. *Elderly:* not exceed 0.5mg/day. **CONTRAINDICATIONS:** sensitivity to benzodiazepines, or any of the drugs excipients; acute pulmonary insufficiency; severe respiratory insufficiency, clinical or biochemical evidence of significant liver disease, sleep apnoea syndrome, myasthenia gravis, severe hepatic insufficiency and acute narrow angle glaucoma. **WARNINGS & PRECAUTIONS:** Interference with Cognitive and Motor Performance, Suicidal Behavior and Ideation, Pregnancy risk, Withdrawal Symptoms. *Precautions:* Worsening of Seizures, Risks of Abrupt Withdrawal, Caution in Renal Impaired Patients, Hypersalivation. **DRUG INTERACTIONS:** Cytochrome P-450 inducers, such as phenytoin, carbamazepine, and phenobarbital, induce clonazepam metabolism, causing an approximately 30% decrease in plasma clonazepam levels. The CNS-depressant action of the benzodiazepine class of drugs may be potentiated by alcohol, narcotics, barbiturates, nonbarbiturate hypnotics, antianxiety agents, the phenothiazines, thioxanthene and butyrophenone classes of antipsychotic agents, monoamine oxidase inhibitors and the tricyclic antidepressants, and by other anticonvulsant drugs. **ADVERSE REACTIONS:** anaphylaxis, Angioedema, incomplete precocious puberty, Impaired concentration, restlessness, confusional state, disorientation, excitability, irritability, aggression, agitation, nervousness, hostility, anxiety, sleep disturbances, nightmares, vivid dreams, psychotic disorders, Somnolence, slowed reaction, muscular hypotonia, dizziness, ataxia, Cardiac failure including cardiac arrest, Respiratory depression, nausea, epigastric symptoms, icaria, pruritus, rash, transient hairloss, pigmentation changes, Muscle weakness, urinary incontinence, erectile dysfunction or loss of libido, Fatigue (tiredness, lassitude), increased risk for falls and fractures, blood dyscrasias and abnormal liver function tests, tremor, sweating, agitation, anxiety, headaches, muscle pain, extreme anxiety.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/CLONOTRIL/FEB 2015/01/AbPI
(Additional information is available on request)