

TORLEVA

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

Abbreviated Prescribing information for TORLEVA (Levetiracetam IP)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Levetiracetam affects intraneuronal Ca^{2+} levels by partial inhibition of N-type Ca currents and by reducing the release of Ca^{2+} from intraneuronal stores. In addition, it partially reverses the reductions in GABA- and glycine-gated currents induced by zinc and β -carbolines. It binds to a specific site in rodent brain tissue (synaptic vesicle protein 2A) believed to be involved in vesicle fusion and neurotransmitter exocytosis.

DOSAGE AND ADMINISTRATION: The tablets must be taken orally, swallowed with a sufficient quantity of liquid and may be taken with or without food. The daily dose is administered in two equally divided doses.

CONTRAINDICATION: Hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients listed in section 2.

WARNINGS & PRECAUTIONS: Renal Impairment, Acute Kidney injury, Blood cell counts, Suicide, Abnormal and aggressive behaviours, Worsening of seizures, Electrocardiogram QT interval prolongation, Paediatric population.

DRUG INTERACTION: Antiepileptic medicinal products: (phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone), Probenecid, Methotrexate, Oral contraceptives (ethinyl-estradiol and levonorgestrel) and other pharmacokinetics interactions, Alcohol.

ADVERSE REACTIONS: Nasopharyngitis, somnolence, headache, fatigue and dizziness, Infection, thrombocytopenia, leukopenia, Pancytopenia, (DRESS), Hypersensitivity (including angioedema and anaphylaxis), neutropenia, agranulocytosis, Hyponatraemia, Anorexia, Weight decreased, weight increase, Depression, hostility/aggression, anxiety, insomnia, nervousness/irritability, Suicide attempt, suicidal ideation, psychotic disorder, abnormal behaviour, hallucination, anger, confusional state, panic attack, affect lability/mood swings, agitation, Completed suicide, personality disorder, thinking abnormal, delirium Convulsion, balance disorder, dizziness, lethargy, tremor, Amnesia, Choreoathetosis, dyskinesia, memory impairment, abnormal/ataxia, paraesthesia, disturbance in attention, Choreoathetosis, dyskinesia, hyperkinesia, gait disturbance, encephalopathy, coordination, Diplopia, vision blurred, Vertigo, Cough, Abdominal pain, diarrhoea, dyspepsia, vomiting, nausea, Pancreatitis, Hepatic failure, Hepatitis, Liver function test, Alopecia, Acute Kidney injury, eczema, pruritus, Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, Muscular weakness, myalgia, Rhabdomyolysis and blood creatine phosphokinase increased, Asthenia/fatigue, Injury.

Marketed BY:



TORRENT PHARMACEUTICALS LTD.

IN/TORLEVA 250,500,1000mg/ APR-21/02/ABPI

(Additional information is available on request)