## LACOSAM

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

Abbreviated Prescribing information for LACOSAM [Lacosamide film coated tablets 50 mg, 100 mg, 150 mg & 200 mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

**PHARMACOLOGICAL PROPERTIES**: Precise mechanism of action unknown in human. From in vitro electrophysiological studies it has found that Lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes and inhibition of repetitive neuronal firing.

**INDICATION:** Lacosamide tablet is indicated as an adjunctive treatment of partial onset seizures in patients  $\geq 17$  years of age.

**DOSAGE AND ADMINISTRATION**: it may be taken with/without food. Partial-Onset Seizures: initial dose should be 50 mg twice daily (100mg per day) and increased at weekly interval by 100mg daily and maximum up to 400mg daily in divided dosing. Patients with mild to moderate renal impairment: no dose adjustment needed; however in patients with severe renal impairment/ESRD maximum 300mg daily can be given. Mild to moderate hepatic impairment: dosing up to 300mg daily can be given; while not recommended in severe hepatic impairment.

## **CONTRAINDICATION:** None.

**WARNINGS & PRECAUTIONS**: suicidal behavior and ideation, dizziness, ataxia, cardiac rhythm and conduction abnormalities, atrial fibrillation and atrial flutter, syncope, withdrawal of antiepileptic drugs, multiorgan hypersensitivity reactions.

**DRUG INTERACTIONS**: Drugs affecting heart conduction system.

**ADVERSE REACTIONS**: Dizziness, ataxia, vomiting, diplopia, nausea, vertigo, vision blurred, diarrhea, fatigue, gait disturbance, asthenia, contusion, skin laceration, headache, somnolence, tremor, nystagmus, balance disorder, memory impairment, depression, pruritus, nephritis, hepatitis, nephritis, delayed hypersensitivity reaction, neutropenia, anemia, palpitations, tinnitus, constipation, dyspepsia, dry mouth, oral hypoaesthesia, irritability, pyrexia, feeling drunk, fall, muscle spasms, paresthesia, cognitive disorder, hypoaesthesia, dysarthria, disturbance in attention, cerebellar syndrome, confusional state, mood altered, depressed mood, agranulocytosis, bradycardia, hallucination, rash.

## **MARKETED BY:**

TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA

IN/LACOSAM/Jun-2015/01/AbPI (Additional information is available on request)