

OLEPTAL

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

Abbreviated Prescribing information for OLEPTAL [Oxcarbazepine 600mg Tablets]

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

PHARMACOLOGICAL PROPERTIES: Oxcarbazepine produce blockade of voltage-sensitive sodium channels, resulting in stabilization of hyperexcited neural membranes, inhibition of repetitive neuronal firing, and diminution of propagation of synaptic impulses. These actions are thought to be important in the prevention of seizure spread in the intact brain.

INDICATION: For use as monotherapy and adjunctive therapy in the treatment of partial seizures in adult patients with epilepsy. It is also indicated as adjunctive therapy in the treatment of partial seizures in children in the age group of 4-16 years with epilepsy.

DOSAGE AND ADMINISTRATION:

Oleptal is recommended as adjunctive and monotherapy in the treatment of partial seizures in adults and as adjunctive treatment for partial seizures in children 4 - 16 years of age group. All dosing should be given in a twice a day (BID) regimen and can be given with or without food.

CONTRAINDICATION: Oxcarbazepine should not be used in patients with a known hypersensitivity to oxcarbazepine or to any of its components.

WARNINGS & PRECAUTIONS: Use cautiously and stop the Oleptal in patients with hyponatremia, anaphylactic reactions and angioedema, with a past history of hypersensitivity reaction to carbamazepine, serious dermatological reactions, association with HLA-B*1502, suicidal behavior and ideation, multi-organ hypersensitivity, hematologic events and seizure control during pregnancy. Drug reaction with eosinophilia and systemic symptoms (DRESS)/multi-organ hypersensitivity and cognitive/neuropsychiatric adverse events then oxcarbazepine should be discontinued.

DRUG INTERACTION: Antiepileptic drugs: carbamazepine, phenobarbital, phenytoin, valproic acid and hormonal contraceptives, calcium antagonists, cimetidine, erythromycin and dextropropoxyphene.

ADVERSE REACTIONS: Dizziness, diplopia, ataxia, vomiting, nausea, somnolence, headache, asthenia, edema legs, weight increase, hypotension, diarrhea, dyspepsia, constipation, gastritis, muscle weakness, insomnia, rhinitis, acne, vertigo, abnormal vision, tremor, abnormal gait, rash, hyponatremia, somnolence, diplopia, dizziness, fatigue, nystagmus, withdrawal symptoms like convulsions, status epilepticus and ataxia..

MARKETED BY:

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(Additional information is available on request)