

ESLIFY

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

Abbreviated Prescribing information for ESLIFY (Eslicarbazepine Acetate 200mg, 400mg, 600mg and 800mgTablets) [Please refer the complete prescribing information available at www.torrentpharma.com].

PHARMACOLOGICAL PROPERTIES: Eslicarbazepine acetate and its active metabolites prevented the development of seizures in nonclinical models predictive of anticonvulsant efficacy in man. In humans, the pharmacological activity of eslicarbazepine acetate is primarily exerted through the active metabolite eslicarbazepine. **INDICATIONS:** Eslicarbazepine is indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalization. **DOSAGE AND ADMINISTRATION:** The recommended starting dose is 400 mg once daily which should be increased to 800 mg once daily after one or two weeks. Eslicarbazepine is not recommended for use in children below 18 years. **CONTRAINDICATIONS:** Hypersensitivity to the active substance, to other carboxamide derivatives (e.g. carbamazepine, oxcarbazepine) or to any of the excipients. Known second or third degree atrioventricular (AV) block. **WARNINGS & PRECAUTIONS:** Central nervous system adverse reactions, such as dizziness and somnolence, which could increase the occurrence of accidental injury; Hyponatremia; decrease the effectiveness of hormonal contraceptives. Suicidal ideation and behavior. Eslicarbazepine should be used with caution in patients with mild to moderate hepatic impairment (Limited clinical data) and is not recommended in patients with severe hepatic impairment, in patients with medical conditions (e.g. low levels of thyroxine, cardiac conduction abnormalities), or when taking concomitant medicinal products known to be associated with PR prolongation. **DRUG INTERACTIONS:** Interact with Phenytoin, Lamotrigine, Topiramate, Carbamazepine, valproate and levetiracetam: Oral contraceptives, Warfarin, Monoamine Oxidase Inhibitors (MAOIs). **ADVERSE REACTIONS:** Anemia, Hypersensitivity, Hypothyroidism, Increased appetite, electrolyte imbalance, hyponatraemia, Insomnia, apathy, depression, nervousness, agitation, attention deficit/hyperactivity disorder, psychomotor retardation, psychotic disorder, Dizziness, Somnolence, Headache, abnormal coordination, disturbance in attention, tremor, dystonia, lethargy, grand mal convulsion, nystagmus, speech disorder, Diplopia, vision blurred, Vision disturbance, eye pain, Vertigo, Ear pain, Palpitations, bradycardia, Hypertension, hypotension, Nausea, Dyspepsia, gastritis, vomiting, abdominal pain, diarrhea, dry mouth, abdominal discomfort, Liver disorder, Rash Alopecia, dry skin, Myalgia, back pain, Menstruation irregular, Fatigue, gait disturbance, Asthenia, malaise, chills, edema peripheral, joint injury and fall.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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

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(Additional information is available on request)