

PREGALIN

For the Use of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for Pregalin (Pregabalin 75, 150 mg capsules I.P.) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pregabalin is a structural derivative of the inhibitory neurotransmitter gamma amino butyric acid (GABA) from anti-epileptics therapeutic class.

INDICATION: It is indicated for the treatment of neuropathic pain in adults.

DOSAGE AND ADMINISTRATION: Pregabalin is given orally with or without food. The dose range is 150 to 600 mg per day given in either two or three divided doses.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Diabetic patients may gain weight with pregabalin's treatment. For the withdrawal of concomitant antiepileptic medicines, once seizure control with pregabalin in the add-on situation has been reached. Pregabalin should be used with caution in congestive heart failure patients. Discontinuation of it may resolve the reaction. Suicidal ideation and behavior have been reported in patients. It may produce constipation with opioid analgesic. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of pregabalin misuse, abuse or dependence. Dosage adjustment is required for the renal impaired patients.

DRUG INTERACTION: Pregabalin may potentiate the effects of ethanol and lorazepam. It appears to be additive in the impairment of cognitive and cross motor function caused by oxycodone.

ADVERSE REACTIONS: Loss of consciousness, confusion, mental impairment, loss of vision, visual blurring or other changes of visual acuity, insomnia, headache, nausea, anxiety, diarrhea, flu syndrome, nervousness, depression, pain, respiratory failure, coma, convulsion, hyperhidrosis, suggestive of physical dependence, nasopharyngitis, appetite increased, euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, dizziness, somnolence, diplopia, vertigo, vomiting, nausea, constipation, muscle cramp, arthralgia, erectile dysfunction, oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, weight increased.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/PREGALIN 75,150mg /Jun-15/01/AbPI

(Additional information is available on request)