

PREGALIN SR

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

Abbreviated Prescribing information for Pregalin SR (Pregabalin sustained release tablets 75 mg, 150 mg, 300 mg) [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).

INDICATION: Pregabalin SR is indicated for management of neuropathic pain.

DOSAGE AND ADMINISTRATION: The starting dose of Pregabalin SR Tablets is 150 mg once daily, administered in the evening. Maximum safe dose of Pregabalin is 600 mg/day. Dose increment should be made at intervals of 7 days of 150mg/day. Pregabalin SR Tablets can be taken with or without food. Pregabalin SR must be swallowed whole with the aid of liquids. It should not be chewed, divided, or crushed.

CONTRAINDICATION: Pregabalin SR is contraindicated in patients with known hypersensitivity to any of its components.

WARNINGS & PRECAUTIONS: Pregabalin may cause life-threatening angioedema with respiratory compromise as per reports; it should be discontinued immediately. Caution should be exercised when prescribing it to patients who have had a previous episode of angioedema. Pregabalin should be discontinued over a minimum of 1 week to avoid seizures, insomnia, nausea, headache and diarrhea. Taking thiazolidinedione, an antidiabetic agent with pregabalin may cause weight gain and peripheral edema in higher frequency. Hence because there are limited data on congestive heart failure patients with New York Heart Association (NYHA) Class III or IV cardiac status, pregabalin should be used with caution in these patients. Patients who are already routinely monitored for ocular conditions should be cautious for visual disturbance. It is associated with decrease in platelet count. Its treatment is known to be associated with mild PR interval prolongation.

ADVERSE REACTIONS: Dizziness, somnolence, thinking abnormal, infection, accidental injury, dry mouth, constipation, flatulence, vomiting, peripheral edema, weight gain, bronchitis, blurred vision, diplopia, fever, asthenia, confusion, urinary incontinence, abdominal pain, heart failure gastroenteritis, and ecchymosis, creatine kinase elevations, arthralgia, leg cramps, myalgia, anxiety, depersonalization, hypertonia, hypesthesia, pruritus, anorgasmia, impotence.

MARKETED BY:



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IN/PREGALIN SR 75,150,300mg /Jun-15/01/AbPI

(Additional information is available on request)