

PREGALIN X SR

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

Abbreviated Prescribing information for PREGALIN X SR ((PREGALIN X SR 75 Pregabalin Sustained Release 75 mg and Methylcobalamin 1500 mcg) and (PREGALIN X SR 150 Pregabalin Sustained Release 150 mg and Methylcobalamin 1500 mcg)) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pregabalin: binds with high affinity to the alpha 2-delta site (an auxiliary subunit of voltage-gated calcium channels) in central nervous system tissues which, may be involved in antinociceptive and antiseizure effects. **Vitamin B12** is required for synthesis of deoxyribonucleic acid (DNA).

INDICATION: For painful neuropathies such as: Diabetic neuropathy, Postherpetic neuralgia, Trigeminal neuralgia, Following nerve entrapment as in prolapsed intervertebral disc, Complex regional pain syndrome, Infective neuropathies, HIV sensory neuropathy, Alcoholic neuropathy, Nutritional neuropathies, Phantom limb pain.

DOSAGE AND ADMINISTRATION: Adults: Once daily with/without food. Dosage above 300 mg/day must be reserved only for those having on-going pain, and tolerating 300mg pregabalin per day. **Renal dysfunction (maximum dose):** Creatinine clearance 30-60 ml/min- 300 mg/day, Creatinine clearance 15-30 ml/min- 150 mg/day, Creatinine clearance <15 ml/min- 75 mg/day.

CONTRAINDICATION: PREGALIN X SR is not advocated to those hypersensitive to the drug or to any of its ingredients.

WARNINGS & PRECAUTIONS: PREGALIN X SR must not be discontinued abruptly due to the possibility of increasing seizure frequency; rapid discontinuation may also result in insomnia, nausea, headache, or diarrhea. Since pregabalin can cause dizziness, somnolence and other manifestations of central nervous system depression, patients should be advised neither to drive nor to operate complex machinery until they have gained sufficient experience on PREGALIN X SR. If vision disturbances occur during pregabalin therapy, medical advice must be sought. PREGALIN X SR must be advocated with caution in heart failure and diabetic patients in view of possibility of edema and weight gain. Diabetic patients taking pregabalin may develop skin ulcerations. PREGALIN X SR must be advocated with due precaution in renal dysfunction. Those with early Leber's disease when treated with vitamin B12 can suffer from severe and swift optic atrophy. PREGALIN X SR should be used during pregnancy and lactation only if the potential benefit justifies the probable risks involved.

DRUG INTERACTION: Gabapentin may slightly decrease the rate of absorption of pregabalin when administered together.

ADVERSE REACTIONS: Dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, "thinking abnormal", asthenia, ataxia, abnormal gait, paresthesias, diplopia, visual field defect, nystagmus, nausea, tremor, vertigo, headache, nervousness, confusion, edema, abdominal pain, allergic reaction, fever, flu syndrome, accidental injury, gastroenteritis, diarrhea, flatulence, increased appetite, constipation, ecchymosis; peripheral edema, arthralgia, leg cramps, myalgia, myasthenia, nervousness, amnesia, speech disorder, incoordination, abnormal gait, confusion, anxiety, depersonalization, hypertonia, hypesthesia, libido decreased, nystagmus, paresthesia, stupor, twitching, euphoria, bronchitis, dyspnea, pruritus, face swelling, conjunctivitis, diplopia, abnormal vision, otitis media, tinnitus, anorgasmia, impotence, urinary frequency, urinary incontinence, pulmonary edema, congestive heart failure, peripheral vascular thrombosis, polycythemia vera, mild transient diarrhea itching, transitory exanthema, feeling of swelling of entire body.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent house, Off Ashram road,

Ahmedabad - 380009, INDIA

IN/ PREGALIN X SR /MAR 2015/01/AbPI

(Additional information is available on request)