

PREGABA M SR 75

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for **PREGABA M SR 75** [Pregabalin Sustained Release and Methylcobalamin Tablets]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Pregabalin binds to an auxiliary subunit ($\alpha 2\text{-}\delta$ protein) of voltage-gated calcium channels in the central nervous system. Synthesis of the myelin coating of peripheral nerves requires adequate availability of vitamin B12. Myelin is a lipoprotein and methylcobalamin (in PREGALIN M SR 75 & 150) participates in the synthesis of both lipid (a phospholipid/ lipid) and the protein components. Lipid synthesis: Methylcobalamin (in PREGALIN M SR 75 & 150) supplies necessary methyl group necessary for phospholipid (also referred to as lecithin, the main constituent of medullary sheath lipids) manufacturing.

INDICATIONS For the treatment of adult patients with peripheral neuropathy.

DOSAGE AND ADMINISTRATION: Pregaba M SR 75 tablet once daily with/without food. Increase dose as necessary to Pregaba M SR 75 bid with/without food. Dosage above 300 mg/day must be reserved only for those having ongoing pain and tolerating 300 mg pregabalin per day. Whilst discontinuing Pregaba M SR 75, the dose of pregabalin must be gradually reduced over 1 week. Do not crush or chew the tablet. Take whole tablet with water.

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

WARNINGS & PRECAUTIONS: Pregabalin may cause weight gain in diabetic patients, dizziness, confusion, and blurred vision, especially in the elderly. It can also lead to renal failure, withdrawal symptoms, and suicidal thoughts, and should be used cautiously in patients with heart failure or a history of substance abuse. Misuse and adverse reactions, including encephalopathy, are possible, and vitamin B12 therapy should be closely monitored for side effects like polycythemia vera.

DRUG INTERACTIONS: Pregabalin has minimal metabolism and does not significantly interact with many drugs, including oral contraceptives and antidiabetics. However, it can enhance the effects of CNS depressants like ethanol and lorazepam, leading to potential respiratory failure or coma. Methylcobalamin (vitamin B12) interactions include reduced serum levels with oral contraceptives and chloramphenicol, while high folic acid doses may mask B12 deficiency.

ADVERSE REACTIONS: Nasopharyngitis, Neutropaenia, Hypersensitivity, Angioedema, allergic reaction, Appetite increased, Anorexia, hypoglycaemia, Euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, Hallucination, panic attack, restlessness, agitation, depression, depressed mood, elevated mood, aggression, mood swings, depersonalisation, word finding difficulty, abnormal dreams, libido increased, anorgasmia, apathy, Disinhibition, Dizziness, somnolence, headache, Ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoaesthesia, sedation, balance disorder, lethargy, Syncope, stupor, myoclonus, loss of consciousness, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, mental impairment, speech disorder, hyporeflexia, hyperaesthesia, burning sensation, ageusia, malaise, Convulsions, parosmia, hypokinesia, dysgraphia, Vision blurred, diplopia, Peripheral vision loss, visual disturbance, eye swelling, visual field defect, visual acuity reduced, eye pain, asthenopia, photopsia, dry eye, lacrimation increased, eye irritation, Vision loss, keratitis, oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness, Vertigo, Hyperacusis, Tachycardia, atrioventricular block first degree, sinus bradycardia, congestive heart failure, QT prolongation, sinus tachycardia, sinus arrhythmia, Hypotension, hypertension, hot flushes, flushing, peripheral coldness, Dyspnoea, epistaxis, cough, nasal congestion, rhinitis, snoring, nasal dryness, Pulmonary oedema, throat tightness, Vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth, Gastrooesophageal reflux disease, salivary

hypersecretion, hypoaesthesia oral, Ascites, pancreatitis, swollen tongue, dysphagia, Rash papular, urticaria, hyperhidrosis, pruritus, Stevens Johnson syndrome, cold sweat, Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, Joint swelling, myalgia, muscle twitching, neck pain, muscle stiffness, Rhabdomyolysis, Urinary incontinence, dysuria, Renal failure, oliguria, urinary retention, Erectile dysfunction, Sexual dysfunction, ejaculation delayed, dysmenorrhoea, breast pain, Amenorrhoea, breast discharge, breast enlargement, gynaecomastia, Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, Generalised oedema, face oedema, chest tightness, pain, pyrexia, thirst, chills, asthenia, Weight increased, Blood creatine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased blood glucose increased, platelet count decreased, blood creatinine increased, blood potassium decreased, weight decreased, White blood cell count decreased.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/PREGABA M SR 75 mg/DEC-18/01/ABPI

(Additional information is available on request)