

## PREGABA M

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

Abbreviated Prescribing information for **PREGABA M** [Pregabalin & Methylcobalamin Capsules]

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://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.. Methylcobalamin is involved in the synthesis of thymidine from deoxyuridine and promotes the synthesis of DNA and RNA by acting as a coenzyme in the formation of methionine from homocysteine. It enhances synthesis of lecithin, a major component of myelin sheath. Methylcobalamin is known to be extensively taken up by the nerve cell organelles than cyanocobalamin in animals. It is also reported to maintain axonal function by promoting nucleic acid and protein synthesis.

**INDICATIONS:** Combination of pregabalin and Methylcobalamin is indicated for management of neuropathic pain.

**DOSAGE AND ADMINISTRATION:** Treatment will be started with a capsule containing pregabalin 150mg with Methylcobalamin 750mcg once daily or a capsule containing pregabalin 75mg with Methylcobalamin 750mcg twice daily. The dose may be increased after an interval of 3 to 7 days. Based on individual patient response and tolerability, the maximum recommended dose is four capsules of pregabalin 150mg with Methylcobalamin 750mcg per day in divided doses..

**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/PREGALIN M 75,150mg/MAY-17/01/ABPI**

(Additional information is available on request)