

PREGEB M 75/PREGALIN M 75/PREGABA M 75

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

Abbreviated Prescribing information for PREGALIN M 75/PREGEB M 75/PREGABA M 75 [Pregabalin and Methylcobalamin capsules I.P.]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Pregabalin:* Pregabalin binds to an auxiliary subunit ($\alpha 2$ - δ protein) of voltage-gated calcium channels in the central nervous system. *Methylcobalamin:* Methylcobalamin is the form of vitamin B12 active in the central nervous system. may exert its neuroprotective effects through enhanced methylation, acceleration of nerve cell growth, or its ability to maintain already healthy homocysteine levels.

INDICATIONS: For the treatment of neuropathic pain in adults

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. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of four capsules of pregabalin 150mg with Methylcobalamin 750mcg per day in divided doses. If pregabalin must be discontinued, it is recommended this should be done gradually over a minimum of 1 week independent of the indication. As pregabalin clearance is directly proportional to creatinine clearance, dose reduction in patients with compromised renal function must be individualised according to creatinine clearance (CL_{Cr}). Elderly patients may require a dose reduction of pregabalin due to a decreased renal function. When pregabalin and opioids will be used in combination, measures to prevent constipation may be considered.

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

WARNINGS & PRECAUTIONS: *Pregabalin:* Some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycaemic medicinal products. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur. SCARs including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported rarely in association with pregabalin treatment. Cases of renal failure have been reported and in some cases discontinuation of pregabalin did show reversibility of this adverse reaction. Pregabalin should be used with caution in elderly cardiovascular compromised patients. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants and the elderly may be at higher risk of severe respiratory depression. Reduce the dose by a fixed amount at each decrement, unless clinical risk is such that rapid withdrawal is needed. Pregabalin use in the first trimester of pregnancy may cause major birth defects in the unborn child. Pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus. Patients should be closely monitored for signs of misuse, abuse, or addiction. Overuse or misuse may result in overdose and/or death. *Methylcobalamin:* It should be given with caution in patients suffering from folate deficiency. Don't attempt vitamin B12 therapy without close supervision by healthcare provider. Do not take vitamin B12 if Leber's disease. It can seriously harm the optic nerve, which might lead to blindness.

DRUG INTERACTIONS: *Pregabalin:* Pregabalin may potentiate the effects of ethanol and lorazepam. In the postmarketing experience, there are reports of respiratory failure, coma and deaths in patients taking pregabalin and opioids and/or other central nervous system (CNS) depressant medicinal products.

Methylcobalamin: Potassium supplements can reduce absorption of vitamin B12 in some people and might contribute to vitamin B12 deficiency. Folic acid, particularly in large doses, can cover up vitamin B12 deficiency, and cause serious health effects.

ADVERSE REACTIONS: Dizziness, somnolence, nasopharyngitis, neutropenia, 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, depersonalization, word finding difficulty, abnormal dreams, libido increased, anorgasmia, apathy, 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, parkinsonism, 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, respiratory depression, vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth, gastrooesophageal reflux disease, salivary hypersecretion, hypoaesthesia oral, ascites, pancreatitis, swollen tongue, dysphagia, elevated liver enzymes, jaundice, hepatic failure, hepatitis, rash popular, urticaria, hyperhidrosis, pruritus, drug dependence, steven-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, dysmenorrhea, 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, creatinine increased, blood potassium decreased, weight decreased, white blood cell count decreased, flu syndrome, nervousness, suicidal ideation, pain, hyperhidrosis, upper respiratory tract infection, peripheral vascular thrombosis, polycythemia vera, itching; transitory exanthema and feeling of swelling of entire body and serious allergic reactions.

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MARKETED BY:

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)