

## PREGABA DM / PREGALIN DM / PREGEB DM 75+20 / 75+30

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

Abbreviated Prescribing information for PREGABA DM / PREGALIN DM / PREGEB DM 75+20 / 75+30  
[Pregabalin, Methylcobalamin & Duloxetine (Delayed Release) Capsules (75mg + 1500mcg + 20mg & 75mg + 1500 mcg + 30mg)]

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** *Pregabalin:* Pregabalin binds to an auxiliary subunit ( $\alpha 2\text{-}\delta$  protein) of voltage-gated calcium channels in the central nervous system. *Duloxetine:* It is a combined serotonin (5-HT) and noradrenaline (NA) reuptake inhibitor. It weakly inhibits dopamine reuptake, with no significant affinity for histaminergic, dopaminergic, cholinergic, and adrenergic receptors. Its dose-dependently increases extracellular levels of serotonin and noradrenaline in various brain areas of animals. *Methylcobalamin:* It normalizes nerve cell conduction by healing damaged nerve cells and restores delayed synaptic transmission and decreased neurotransmitters to normal. It also improves the excitability of nerve fibres and thus improves neurotransmission.

**INDICATIONS:** It is indicated for treatment of Patients with Diabetic Peripheral Neuropathic pain and Coexistent Vitamin B12 Deficiency.

**DOSAGE AND ADMINISTRATION:** One capsule once daily, preferably after a meal. FDC use is not recommended in patients with severe renal impairment or on dialysis unless individual components are dose-adjusted accordingly.

**CONTRAINDICATION:** Hypersensitivity to any of the active substances (pregabalin, duloxetine, or methylcobalamin) or to any of the excipients in the formulation. Patients with a history of angioedema, rhabdomyolysis, or hypersensitivity reactions (e.g., rash, pruritus, urticaria) associated with similar agents. Patients with severe renal impairment (creatinine clearance  $<30$  mL/min), including those with chronic kidney disease stages 4 and 5, or those requiring dialysis. Patients with severe hepatic impairment or any clinically significant liver disease. Uncontrolled hypertension, as this may increase the risk of hypertensive crisis. Concomitant use with non-selective, irreversible monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuing an MAOI. Patients with a history of major depressive disorder, suicidal ideation, or suicidal behavior. Presence of cardiac conduction abnormalities such as atrioventricular (AV) block, chronic heart failure (NYHA Class III–IV), or acute decompensated heart failure. Known diagnosis of chronic obstructive pulmonary disease (COPD) or another significant pulmonary dysfunction. Patients experiencing significant fluid retention or peripheral edema (e.g., in the legs, feet, arms, or hands) that may worsen with pregabalin. Patients with known or suspected visual disturbances, such as reduced visual acuity, that may be drug induced.

**WARNINGS & PRECAUTIONS:** This FDC contains both pregabalin and duloxetine, agents associated with an increased risk of suicidal ideation and behaviour. Patients should be closely monitored during treatment initiation and dose adjustments. Dizziness, somnolence, confusion, mental impairment, and loss of consciousness may occur with this FDC. These effects may increase the risk of falls and injuries, especially in elderly patients. Pregabalin in the FDC has been associated with reports of misuse, abuse, and dependence, particularly in individuals with a history of substance abuse. Patients should be observed for symptoms such as tolerance, dose escalation, or drug-seeking behaviour. Abrupt discontinuation of this FDC may lead to withdrawal symptoms including insomnia, anxiety, headache, nausea, dizziness, depression, pain, and seizures. Gradual tapering is recommended prior to cessation. Hypersensitivity reactions including angioedema have been reported with pregabalin and methylcobalamin. Discontinue immediately if signs such as facial or upper airway swelling occur.

**DRUG INTERACTIONS:** *Pregabalin:* Pregabalin may potentiate the effects of ethanol and lorazepam. In the post marketing 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. *Duloxetine:* Due to the risk of serotonin syndrome, it should not be used in combination with nonselective, irreversible monoamine oxidase inhibitors (MAOIs) or within at least 14 days of discontinuing treatment with an MAOI. The concomitant use of Duloxetine with selective, reversible MAOIs, like moclobemide, is not recommended. Caution is advisable if Duloxetine is used concomitantly with serotonergic agents. Caution should be exercised when duloxetine is combined with oral anticoagulants or antiplatelet agents due to a potential increased risk of bleeding attributable to a pharmacodynamic interaction. Because CYP1A2 is involved in duloxetine metabolism, concomitant use of duloxetine with potent inhibitors of CYP1A2 is likely to result in higher concentrations of duloxetine. *Methylcobalamin:* Absorption of vitamin B12 from the gastrointestinal tract may be reduced by neomycin,

aminosalicylic acid, histamine H2-antagonists and colchicine. Serum concentrations may be decreased by concurrent administration of oral contraceptives.

**ADVERSE REACTIONS:** Nasopharyngitis, neutropenia, hypersensitivity, angioedema, allergic reaction, appetite increased, euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, hallucination, panic attack, dizziness, somnolence, headache, ataxia, coordination abnormal, tremor, syncope, stupor, myoclonus, vision blurred, diplopia, peripheral vision loss, visual disturbance, keratitis, vertigo, hyperacusis, tachycardia, atrioventricular block first degree, QT prolongation, hypotension, dyspnoea, pulmonary oedema, vomiting, nausea, gastroesophageal reflux disease, ascites, elevated liver enzymes, Stevens Johnson syndrome, rhabdomyolysis, urinary incontinence, erectile dysfunction, amenorrhoea, edema peripheral, weight increased, laryngitis, hypothyroidism, hyperglycaemia, SIADH, insomnia, agitation, libido decreased, suicidal behaviour, bruxism, lethargy, paraesthesia, akathisia, dysgeusia, restless legs syndrome, extra-pyramidal symptoms, mydriasis, glaucoma, tinnitus, palpitations, atrial fibrillation, hypertensive crisis, interstitial lung disease, stomatitis, haematochezia, rash, warmth, diaphoresis, drowsiness, acidity, dry mouth, mouth ulcers, constipation, sedation, hypoglycemia, common cold, diarrhea, itching, sneezing, etc.

**MARKETED BY:**



Torrent Pharmaceuticals Limited.

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