

## PREGEB D/ PREGABA-D/ PREGALIN D

**“To be sold by retail on the prescription of a R.M.P. only”**

Abbreviated Prescribing information for PREGEB D/ PREGABA-D/ PREGALIN D [Pregabalin and Duloxetine Capsules]

[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 ( $\alpha$ - $\delta$  protein) of voltage-gated calcium channels in the central nervous system. ***Duloxetine:*** Duloxetine 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. Duloxetine dose-dependently increases extracellular levels of serotonin and noradrenaline in various brain areas of animals.

**DOSAGE AND ADMINISTRATION: Dosage:** The recommended dose range is pregabalin 50 mg + duloxetine 20 mg to pregabalin 150 mg + duloxetine 60 mg per day given as single dose or in two divided doses. **Administration:** Pregabalin and duloxetine may be taken with or without food. Pregabalin and duloxetine is for oral use only.

**CONTRAINDICATION:** Known hypersensitivity to pregabalin, duloxetine or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. These interactions may include hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued serotonin reuptake inhibitors and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome and Uncontrolled Narrow-Angle Glaucoma

**WARNINGS & PRECAUTIONS: Pregabalin:** Angioedema, Hypersensitivity, Increased Risk of Adverse Reactions with Abrupt or Rapid Discontinuation, Suicidal Behavior and Ideation, Peripheral Edema, Dizziness and Somnolence, Weight Gain, Tumorigenic Potential, Ophthalmological Effects, Creatine Kinase Elevations, Decreased Platelet Count, PR Interval Prolongation **Duloxetine:** Suicidal Thoughts and Behaviors in Children, Adolescents, and Young Adults, Hepatotoxicity, Orthostatic Hypotension, Falls and Syncope, Serotonin Syndrome, Abnormal Bleeding, Severe Skin Reactions, Discontinuation of Treatment with Duloxetine, Activation of Mania/Hypomania, Angle-Closure Glaucoma, Seizures, Effect on Blood Pressure, Hyponatremia, Use in Patients with Concomitant Illness, Hepatic Impairment, Severe Renal Impairment, Glycemic Control in Patients with Diabetes, Urinary Hesitation and Retention

**DRUG INTERACTIONS: Pregabalin:** there are no pharmacokinetic interactions between pregabalin and the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate. Important pharmacokinetic interactions would also not be expected to occur between pregabalin and commonly used antiepileptic drugs. Multiple oral doses of pregabalin were co-administered with oxycodone, lorazepam, or ethanol. Although no pharmacokinetic interactions were seen, additive effects on cognitive and gross motor functioning were seen when pregabalin was coadministered with these drugs. **Duloxetine:** Inhibitors of CYP1A2, Inhibitors of CYP2D6, Dual Inhibition of CYP1A2 and CYP2D6, Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin), Lorazepam, Temazepam, Drugs that Affect Gastric Acidity, Drugs Metabolized by CYP1A2, Drugs Metabolized by CYP2D6, Drugs Metabolized by CYP2C9, Drugs Metabolized by CYP3A,

Monoamine Oxidase Inhibitors, Serotonergic Drugs, Triptans, Alcohol, CNS Drugs, Drugs Highly Bound to Plasma Protein

**ADVERSE REACTIONS:** **Pregabalin:** Nasopharyngitis, Neutropaenia, Hypersensitivity, 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, loss of consciousness, psychomotor hyperactivity, dyskinesia, 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, Elevated liver enzymes, Jaundice, 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 **Duloxetine:** Laryngitis, Anaphylactic reaction, Hypersensitivity disorder, Hypothyroidism, Decreased appetite, Hyperglycaemia (reported especially in diabetic patients), Dehydration, Hyponatraemia, SIADH, Insomnia, Agitation, Libido decreased, Anxiety, Orgasm abnormal, Abnormal dreams, Suicidal ideation, Sleep disorder, Bruxism, Disorientation, Apathy, Suicidal behaviour, Mania, Hallucinations, Aggression and anger, Serotonin syndrome, Convulsion, Psychomotor restlessness, Extra-pyramidal symptoms, Blurred vision, Mydriasis, Visual impairment, Glaucoma, Tinnitus, Tachycardia, Supraventricular arrhythmia, mainly atrial fibrillation, Blood pressure increase, Flushing, Peripheral coldness, Syncope, Hypertension, Orthostatic hypotension, Hypertensive crisis, Throat tightness Epistaxis, Interstitial lung disease, Eosinophilic pneumonia, Gastrointestinal haemorrhage, Gastroenteritis, Eructation, Gastritis, Dysphagia, Hepatitis, Elevated liver enzymes, (ALT, AST, alkaline phosphatase), Acute liver injury, Muscle spasm, Muscle tightness, Muscle twitching, Trismus, Dysuria, Pollakiuria, Urinary retention, Urinary hesitation, Nocturia, Polyuria, Urine flow decreased, Urine odour abnormal, Erectile dysfunction, Ejaculation disorder, Ejaculation delayed, Gynaecological haemorrhage, Menstrual disorder, Sexual dysfunction, Testicular pain, Menopausal symptoms, Galactorrhoea, Hyperprolactinaemia, Postpartum haemorrhage, Falls, Fatigue, Chest pain, Feeling abnormal.

**MARKETED BY:**



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**IN/PREGEB D/ PREGABA-D/ PREGALIN D 75,50,20,30 mg/Oct21/01/ABPI**

(Additional information is available on request)