**PREGABA NT**

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**
Abbreviated Prescribing information for PREGABA NT (Pregabalin and Nortriptyline Tablets)

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

**PHARMACOLOGICAL PROPERTIES**:

**Mechanism of action:** Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system. Nortriptyline is a tricyclic antidepressant with actions and uses similar to these of Amitriplyline. It is the principal active metabolite of Amitriplyline.

**DOSAGE AND ADMINISTRATION:** One tablet once daily or as directed by physician.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients of the tablet; Recent myocardial infarction, any degree of heart block or other cardiac arrhythmias, severe liver disease, mania; contra-indicated for the nursing mother and for children under the age of six years.

**WARNINGS & PRECAUTIONS**: Some diabetic patients who gain weight on PREGABA NT treatment may need to adjust hypoglycaemic medicinal products; Hypersensitivity; Special care should be taken as the PREGABA NT is associated with dizziness, somnolence, loss of consciousness, confusion and mental impairment, vision-related effects, renal failure, withdrawal of concomitant anti-epileptic medicinal products, withdrawal symptoms, congestive heart failure, treatment of central neuropathic pain due to spinal cord injury, suicidal ideation and behaviour, reduced lower gastrointestinal tract function, misuse, abuse potential or dependence, and encephalopathy.

**DRUG INTERACTION:** It can interact with ethanol and lorazepam, monoamine oxidase inhibitors, adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine, guanethidine, debrisoquine, bethanidine, clonidine, Barbiturates, alcohol, cimetidine, fluoxetine, phenothiazines, carbamazepine, propafenone, flecainide and encainide, quinidine, anticholinergic drugs, valproic acid.

**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, elevated liver enzymes, jaundice, hepatic failure, hepatitis, 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, blood glucose increased, platelet count decreased, blood creatinine increased, blood potassium decreased, weight decreased, white blood cell count decreased, Bone-marrow depression, including agranulocytosis; aplastic anaemia; eosinophilia; purpura; thrombocytopenia, Petechiae, itching, photosensitisation (avoid excessive exposure to sunlight), drug fever, cross-sensitivity with other tricyclic drugs, syndrome of inappropriate secretion of antidiuretic hormone, Delusions, drowsiness, nightmares, hypomania, exacerbation of psychosis, impotence, Numbness, tingling, tremors, extrapyramidal symptoms; seizures, alteration of EEG patterns, tinnitus, sublingual adenitis or gingivitis, disturbance of accommodation, paralytic ileus, delayed micturition, dilation of the urinary tract, Palpitation, Myocardial infarction, arrhythmias, heart block, stroke, epigastric distress, peculiar taste, stomatitis, abdominal cramps, black tongue, paralytic ileus, parotid swelling, altered liver function, liver necrosis, alopecia, nocturia, testicular swelling, sweating; weakness.

**MARKETED BY:**

TORRENT PHARMACEUTICALS LTD.

**IN/PREGALIN NT 75,10/DEC-19/01/ABPI**
(Additional information is available on request)