

PREGALIN NT 50/10

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for **PREGALIN NT 50/10** (Pregabalin 50mg and Nortriptyline 10mg Tablets)

[Please refer the complete prescribing information available at 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. Nortriptyline is a tricyclic antidepressant with actions and uses similar to these of Amitriptyline. It is the principal active metabolite of Amitriptyline.

INDICATION: It is indicated for the treatment of neuropathic pain.

DOSAGE AND ADMINISTRATION: Recommended oral dose of PREGALIN NT 50/10 tablet is twice a day. It is advised to consult doctor for the dosage, as the frequency also depends on the patient's condition.

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 PREGALIN NT 50/10 treatment may need to adjust hypoglycaemic medicinal products; Hypersensitivity; Special care should be taken as the PREGALIN NT 50/10 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.

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IN/ PREGALIN NT 50/10 /MAR-2026/02/ABPI

(Additional information is available on request)