

Pregalin NT

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

Abbreviated Prescribing information for **Pregalin NT** [FDC of Pregabalin 75mg and Nortriptyline 10mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Pregabalin:* It is a gamma-aminobutyric acid analogue which belongs to the anti-epileptic pharmacotherapeutic group. It binds to an auxiliary subunit ($\alpha 2\text{-}\delta$ protein) of voltage-gated calcium channels in the central nervous system. *Nortriptyline:* It is a tricyclic antidepressant and its principle active metabolite is Amitriptyline. Its actions and uses similar to these of amitriptyline.

INDICATION: For treatment of diabetic neuropathy, post-herpetic neuralgia and fibromyalgia.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician. Kindly follow physician's advice.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients of the tablet. It is contraindicated in patients with recent myocardial infarction, any degree of heart block or other cardiac arrhythmias, severe liver disease, mania, for the nursing mother and for children under the age of six years.

WARNINGS & PRECAUTIONS: *Pregabalin:* In diabetic patients, it may cause 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 behavior, reduced lower gastrointestinal tract function, misuse, abuse potential or dependence and encephalopathy. *Nortriptyline:* It patients should be closely monitored for suicide/suicidal thoughts or clinical worsening. On abrupt cessation of therapy, withdrawal symptoms, including insomnia, irritability and excessive perspiration may occur. Its use in schizophrenic patients may cause an exacerbation of the psychosis. It may emerge manic symptoms and may cause behavioral changes may occur in children. Its use should be avoided in patients with narrow angle glaucoma or symptoms suggestive of prostatic hypertrophy.

DRUG INTERACTIONS: *Pregabalin:* It may potentiate the effects of ethanol and lorazepam. It appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone. *Nortriptyline:* Hyperpyretic crises, severe convulsions and fatalities have occurred when similar tricyclic antidepressants were used monoamine oxidase inhibitors. Hence, under no circumstances should nortriptyline be given concurrently with, or within two weeks of cessation of monoamine oxidase inhibitors. It should not be given with sympathomimetic agents such as adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine. It may decrease the antihypertensive effect of guanethidine, debrisoquine, bethanidine and possibly clonidine. Concurrent administration of reserpine has been shown to produce a 'stimulating' effect in some depressed patients. Barbiturates may increase the rate of metabolism of nortriptyline. Concurrent use of anaesthetics may increase the risk of arrhythmias and hypotension. So, it should be discontinued before surgery. It may potentiate the CNS depressant effect of alcohol. It is metabolized by hepatic cytochrome P450IID6 isoenzyme, hence drugs which metabolize with system may lead to drug interaction. Concomitant therapy with other drugs that are metabolised by this isoenzyme, including other antidepressants, phenothiazines, carbamazepine, propafenone, flecainide and encainide, or that inhibit this enzyme (eg, quinidine), should be approached with caution. Dose adjustment may be required while co-administering anticholinergic drugs.

ADVERSE REACTIONS: *Pregabalin:* dizziness, somnolence, Nasopharyngitis, Appetite increased, Euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, headache, Vision blurred, diplopia, Vertigo, Vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth. Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, Erectile dysfunction, Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, Weight increased. After discontinuation of short-term and long-term treatment insomnia, headache, nausea,

anxiety, diarrhoea, flu syndrome, convulsions, nervousness, depression, pain, hyperhidrosis and dizziness, suggestive of physical dependence may occur.

Nortriptyline: Tachycardia, palpitation, myocardial infarction, confusional states (especially in the elderly) with hallucinations, disorientation, delusions; anxiety, restlessness, agitation, insomnia, peripheral neuropathy; extrapyramidal symptoms, sublingual adenitis or gingivitis, rash, petechiae, urticaria, itching, photosensitization, oedema, bone-marrow depression, including agranulocytosis; aplastic anaemia; eosinophilia; purpura; thrombocytopenia, anorexia, epigastric distress, diarrhea, peculiar taste, stomatitis, abdominal cramps, black tongue, gynaecomastia, jaundice (simulating obstructive); altered liver function, hepatitis and liver necrosis and withdrawal symptoms.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

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(Additional information is available on request)