GABATOR NT

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory abbreviated prescribing information for GABATOR NT (Gabapentin & Nortriptyline Hydrochloride Tablets)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: ***Gabapentin:*** Gabapentin readily enters the brain and prevents seizures in a number of animal models of epilepsy. Gabapentin does not possess affinity for either GABAA or GABAB receptor nor does it alter the metabolism of GABA. It does not bind to other neurotransmitter receptors of the brain and does not interact with sodium channels. Gabapentin binds with high affinity to the α2δ (alpha-2-delta) subunit of voltage-gated calcium channels and it is proposed that binding to the α2δ subunit may be involved in gabapentin's anti-seizure effects in animals. Broad panel screening does not suggest any other drug targets other than α2δ. ***Nortriptyline:*** Nortriptyline is a tricyclic antidepressant with actions and uses similar to these of Amitriptyline. It is the principal active metabolite of Amitriptyline.

INDICATION: GABATOR NT is indicated for neuropathic pain in adults.

DOSAGE AND ADMINISTRATION: Film coated tablet, *Method of administration*: For oral use. Gabapentin can be given with or without food and should be swallowed whole with sufficient fluid intake (e.g. a glass of water).

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

WARNINGS & PRECAUTIONS: ***Gabapentin:*** Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), Anaphylaxis, Suicidal ideation and behavior, Acute pancreatitis, Seizures, Concomitant use with opioids and other CNS depressants, Respiratory depression, Elderly (over 65 years of age), Paediatric population, Abuse and Dependence. ***Nortriptyline:*** if you feel suicidal or aggressive, agitated, overactive, or suffer from schizophrenia, heart disease, thyroid condition, history of epilepsy, high pressure in the eyes (glaucoma), enlarged prostate, electroconvulsive therapy (electric shock); anaesthetic, e.g. for an operation and if you are pregnant, think you might be pregnant or planning to become pregnant or breast-feeding you should not take Nortriptyline tablets unless your doctor tells you to.

DRUG INTERACTIONS: ***Gabapentin:*** Respiratory depression and/or sedation and death associated with Gabapentin when co-administered with CNS depressants including opioids. Gabapentin with morphine increased in AUC by 44% compared to gabapentin administered without morphine. Co-administration of gabapentin with antacids containing aluminium and magnesium, reduces gabapentin bioavailability up to 24%. It is recommended that gabapentin be taken at the earliest two hours following antacid administration. Renal excretion of gabapentin is unaltered by probenecid. A slight decrease in renal excretion of gabapentin that is observed when it is co-administered with cimetidine is not expected to be of clinical importance. ***Nortriptyline:*** Hyperpyretic crises, severe convulsions and fatalities have occurred when similar tricyclic antidepressants were used in such combinations. Nortriptyline should not be given with sympathomimetic agents such as adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine. Nortriptyline may decrease the antihypertensive effect of guanethidine, debrisoquine, bethanidine and possibly clonidine. Barbiturates may increase the rate of metabolism of nortriptyline. Anaesthetics given during tricyclic antidepressant therapy may increase the risk of arrhythmias and hypotension. Tricyclic antidepressants may potentiate the CNS depressant effect of alcohol. The potentiating effect of excessive consumption of alcohol may lead to increased suicidal attempts or overdosage, especially in patients with histories of emotional disturbances or suicidal ideation. 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. Nortriptyline plasma concentration can be increased by valproic acid. Nortryptiline should be used cautiously when co-administered with buprenorphine/opioids as the risk of serotonin syndrome, a potentially life-threatening condition, is increased.

ADVERSE REACTIONS: *Gabapentin:* viral infection, pneumonia, respiratory infection, urinary

tract infection, infection, otitis media, leucopenia, thrombocytopenia, allergic reactions (e.g. urticaria), hypersensitivity syndrome (a systemic reaction with a variable presentation that can include fever, rash, hepatitis, lymphadenopathy, eosinophilia, and sometimes other signs and symptoms), anaphylaxis, anorexia, increased appetite, hyperglycaemia (most often observed in patients with diabetes), hypoglycaemia (most often observed in patients with diabetes), hyponatraemia, hostility, confusion and emotional lability, depression, anxiety, nervousness, thinking abnormal, agitation, hallucinations, suicidal ideation, somnolence, dizziness, ataxia, convulsions, hyperkinesias, dysarthria, amnesia, tremor, insomnia, headache, sensations such as paresthesia, hypaesthesia, coordination abnormal, nystagmus, increased, decreased, or absent reflexes, hypokinesia, mental impairment and loss of consciousness. *Nortriptyline:* Bone-marrow depression, rash, petechiae, urticaria, itching, oedema, fever, gynaecomastia in the male, numbness, tingling, paraesthesia of extremities; in co-ordination, ataxia, tremors; peripheral neuropathy; extrapyramidal symptoms; seizures, alteration of EEG patterns; tinnitus; dizziness; headache, dry mouth, mydriasis, constipation, paralytic ileus; urinary retention, delayed micturition, dilation of the urinary tract, hypotension, hypertension, tachycardia, palpitation, myocardial infarction, arrhythmias, heart block, stroke, flushing, nausea and vomiting, anorexia, epigastric distress, diarrhoea; peculiar taste, stomatitis, abdominal cramps, black tongue, constipation, paralytic ileus parotid swelling, jaundice, altered liver function; hepatitis and liver necrosis, alopecia, breast enlargement and galactorrhoea in the female; testicular swelling; elevation or depression of blood sugar levels; weight gain or loss, sweating; weakness, fatigue; alopecia. Confusional states, disorientation, delusions; anxiety, restlessness, drowsiness, agitation; insomnia, panic, nightmares; hypomania; exacerbation of psychosis; increased or decreased libido, cases of suicidal ideation and suicidal behaviours have been reported during nortriptyline therapy or early treatment discontinuation,

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)