

## Summary of prescribing information for GABAPIN NT tablets

**Active Ingredient:** each film-coated tablet of GABAPIN NT contains: gabapentin 100mg/400mg + Nortriptyline Hydrochloride IP equivalent to nortriptyline 10mg/10mg. **Indication:** for the treatment of pain associated with peripheral neuropathic conditions in adults. **Dosage:** should be taken orally with or without food. GABAPIN NT 400 therapy should be initiated as a single tablet taken on day 1, one tablet to be taken twice daily day 2, one tablet thrice a day (t.i.d.) on day 3 and thereafter the dose can be titrated up as needed for pain relief by successively adding one tablet to existing t.i.d. regimen to reach the maximum recommended dose of 2400 mg gabapentin or 60 mg nortriptyline per day. Titrate the dosage to a maintenance level that is well tolerated as well as effective. If GABAPIN NT dose is reduced, discontinued or substituted with an alternative medication, this should be done gradually over a minimum of 1 week (a longer period may be needed at the discretion of the prescriber). **Contraindications:** Hypersensitivity to gabapentin or nortriptyline, other tricyclic antidepressants, or to any ingredient in the formulation, pregnancy and lactation, acute recovery period after myocardial infarction, Concomitant use with monoamine oxidase inhibitors. **Warning and precautions:** Gabapentin: Drug Reaction with Eosinophilia and Systemic Symptoms (Multiorgan hypersensitivity): Discontinue if alternative etiology is not established. Anaphylaxis and Angioedema: Discontinue. Driving Impairment; Somnolence/Sedation and Dizziness: Warn patients not to drive until they have gained sufficient experience. Increased seizure frequency may occur in patients with seizure disorders if gabapentin is abruptly discontinued. Suicidal Behavior and Ideation: Monitor. Neuropsychiatric Adverse Reactions in Children 3 to 12 Years of Age: Monitor for events. Nortriptyline: clinical worsening and suicide risk. History of seizure: monitor. Serotonin Syndrome: when coprescribed with other serotonergic drugs. Angle closure glaucoma. **Pregnancy & Lactation:** contraindicated, as mentioned earlier. **Interaction:** Gabapentin: Concentrations increased by morphine; may need dose adjustment. Nortriptyline: anticholinergic drugs and sympathomimetic drugs: Close supervision and careful adjustment required. Cimetidine and tricyclic antidepressants: can produce clinically significant increases in the plasma concentrations of the tricyclic antidepressant. Response to alcohol may be exaggerated. Reserpine: with a tricyclic antidepressant has been shown to produce a “stimulating” effect in some depressed patients. Chlorpropamide (250 mg/day): case of significant hypoglycemia has been reported in a type II diabetic patient with nortriptyline (125 mg/day). Cytochrome P450 2D6 inhibitors: may require lower doses than usually prescribed. **Adverse reactions:** Most common Somnolence, dizziness, ataxia, fatigue, and nystagmus, viral infection, fever, nausea and/or vomiting, somnolence, and hostility. Nortriptyline: most common hypotension, sedation, dry mouth, seizures, weight gain, gynecomastia in the male, and breast enlargement and galactorrhea in the female. **Overdose:** Gabapentin: symptoms double vision, slurred speech, drowsiness, lethargy, and diarrhea, coma. Management: general supportive care. Gabapentin can be removed by hemodialysis. Although hemodialysis may be indicated by the patient’s clinical state or in patients with significant renal impairment. Nortriptyline: symptoms cardiac dysrhythmias, severe hypotension, shock, congestive heart failure, pulmonary edema, convulsions, and CNS depression, including coma. Changes in the electrocardiogram, particularly in QRS axis or width, confusion, restlessness, disturbed concentration, transient visual hallucinations, dilated pupils, agitation, hyperactive reflexes, stupor, drowsiness, muscle rigidity, vomiting, hypothermia, hyperpyrexia. Management: There is no specific antidote. Symptomatic therapy and basic management of airway and respiration. Gastric lavage with activated charcoal should be done. Vital sign monitoring along with general symptomatic and supportive care is required. The electrocardiogram, pulse, blood pressure, neurobehavioral status of the patient and his intake and output balance must be monitored. Intravenous sodium bicarbonate should be used to maintain the serum pH in the range of 7.45 to 7.55. Dysrhythmias unresponsive to sodium bicarbonate therapy/hyperventilation may respond to lidocaine, bretylium or phenytoin. Hemoperfusion may be beneficial in acute refractory cardiovascular instability in patients with acute toxicity. In patients with CNS depression, early intubation is advised because of the potential for abrupt deterioration. Seizures should be controlled with benzodiazepines.

Prepared on 24<sup>th</sup> Feb 2020.

It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. [productqueries@intaspharma.com](mailto:productqueries@intaspharma.com)