Abridged Prescribing Information:

Active Ingredient: PREGABID NT 50/75 tablets contain pregabalin 50mg / 75 mg +Nortriptyline 10mg

Indication: Treatment of pain associated with various neuropathic conditions in adults such as: Diabetic peripheral neuropathy, Post-herpetic neuralgia, Neuropathic low back pain, Spinal cord injury-associated pain, Central post-stroke pain, Trigeminal neuralgia. **Dosage & Administration:** Start with one PREGABID NT 50 tablet orally thrice daily (t.i.d.) or PREGABID NT 75 twice daily for the first 3-7 days (daily dose: pregabalin 150 mg + nortriptyline 30 mg). Thereafter, depending on patient's response and tolerability, dose can be increased to daily dose: pregabalin 300 mg + nortriptyline 60 mg. For pain of post-herpetic neuralgia: after 2-4 weeks, if pain relief is insufficient and PREGABID NT 50 2 tablets t.i.d or PREGABID NT 75 2 tablets b.i.d. have been tolerated well, dose may be increased further cautiously to a maximum of daily dose: pregabalin 450 mg + nortriptyline 90 mg. **Warnings & Precautions:** Withdrawal: Discontinuation of PREGABID NT should be done over a minimum of 1 week. Tumorigenic potential: In lifetime carcinogenicity study in mice, pregabalin was associated with a high incidence of hemangiosarcoma. The clinical significance of this is unknown. PREGABID NT may cause dizziness, somnolence, blurred vision, and other central nervous system (CNS) signs and symptoms. Pregabalin may cause edema and weight gain. Angioedema (e.g., swelling of the throat, head and neck) can occur, and may be associated with life-threatening respiratory compromise requiring emergency treatment. Patients who require concomitant treatment with CNS depressants such as opioids or benzodiazepines should be informed that they may experience additive CNS side effects, such as somnolence. Consuming alcohol while taking PREGABID NT should be avoided **Pregnancy & Lactation:** Pregnancy Category C. Breast-feeding is avoidable if taking PREGABID NT. **Drug Interaction:** Pregabalin may potentiate the effects of ethanol and lorazepam. Nortriptyline: Close supervision and careful adjustment of the dosage are required when nortriptyline hydrochloride is used with other anticholinergic drugs and sympathomimetic drugs. Concurrent administration of cimetidine and tricyclic antidepressants can produce clinically significant increases in the plasma concentrations of the tricyclic antidepressant. Administration of reserpine during therapy with a tricyclic antidepressant has been shown to produce a "stimulating" effect in some depressed patients. Drugs Metabolized by cytochrome P450 2D6 (CYP2D6) – The biochemical activity of the drug metabolizing isozyme CYP2D6 (debrisoquin hydroxylase) is reduced in a subset of the caucasian population (about 7% to 10% of caucasians are so called "poor metabolizers"); reliable estimates of the prevalence of reduced CYP2D6 isozyme activity among Asian,. Poor metabolizers have higher than expected plasma concentrations of tricyclic antidepressants (TCAs) when given usual doses. Depending on the fraction of drug metabolized by CYP2D6, the increase in plasma concentration may be small, or quite large (8-fold increase in plasma AUC of the TCA). The drugs that inhibit CYP2D6 include some that are not metabolized by the enzyme (quinidine; cimetidine) and many that are substrates for CYP2D6 (many other antidepressants, phenothiazines, and the Type 1C antiarrhythmics propafenone and flecainide). Nevertheless, caution is indicated in the co-administration of TCAs with any of the SSRIs and also in switching from one class to the other. Of particular importance, sufficient time must elapse before initiating TCA treatment in a patient being withdrawn from fluoxetine, given the long half-life of the parent and active metabolite (at least 5 weeks may be necessary). Concomitant use of TCAs with drugs that can inhibit cytochrome CYP2D6 may require lower doses than usually prescribed for either the TCA or the other drug. **Adverse Reactions:** The most commonly adverse events for pregabalin included dizziness, somnolence, peripheral edema, headache, blurred vision and constipation. The majority (85%) of these (and other) adverse events were of mild-to-moderate intensity. The most commonly reported side effects with nortriptyline are hypotension, sedation, dry mouth, seizures, weight gain, gynecomastia in the male, and breast enlargement and galactorrhea in the female. **Overdose:** There is no specific antidote for overdose with pregabalin. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; usual precautions should be observed to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient. Hemodialysis results in significant clearance of pregabalin (approximately 50% in 4 hours) and may be required in some cases. Treatment for nortriptyline overdose: Symptomatic and supportive therapy is recommended. Activated charcoal may be more effective than emesis or lavage to reduce absorption. *(For details, please refer full prescribing information)*

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