For the use of registered medical practitioner or a hospital or a laboratory.

Active Ingredient: Each film-coated bilayered tablet of Pregabid Trio contains Pregabalin 75 mg (Prolonged Release), Methylcobalamin 1500 mcg and Nortriptyline Hydrochloride 10 mg. **Indication:** For the treatment of patient with diabetic peripheral neuropathic pain with coexistent Vitamin B12 Deficiency. **Dosage:** One tablet once daily orally or as directed by physician. **Contraindications:** Known hypersensitivity to any of the active constituents. **Warnings & Precautions:** *Patients with major depressive disorder (MDD)* Both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. *Diabetic patients* In accordance with current clinical practice, some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycaemic medicinal products. *Hypersensitivity reactions* There have been reports of experience of hypersensitivity reactions, including cases of angioedema. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur. *Dizziness, somnolence, loss of consciousness, confusion, and mental impairment* Pregabalin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. There have also been reports of loss of consciousness, confusion and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicinal product. *Vision-related effects* In the clinical studies, the incidence of visual acuity reduction and visual field changes was greater in pregabalin-treated patients than in placebo-treated patients. Visual adverse reactions have also been reported, including loss of vision, visual blurring or other changes of visual acuity, many of which were transient. Nortriptyline: clinical worsening and suicide risk. History of seizure: monitor. Serotonin Syndrome: when coprescibed with other serotonergic drugs. Angle closure glaucoma. **Interactions:** Pregabalin: it is unlikely to produce, or be subject to, pharmacokinetic interactions**.** Nortryptiline: Administration of reserpine during therapy with a tricyclic antidepressant has been shown to produce a "stimulating" effect in some depressed patients. Close supervision and careful adjustment of the dosage are required when nortriptyline 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. The patient should be informed that the response to alcohol may be exaggerated. Methylcobalamin: Absorption of vitamin B_{12} from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H_2 receptor antagonists, omeprazole, and colchicine. Serum concentrations may be decreased by use of oral contraceptives. Many of these interactions are unlikely to be of clinical significance. **Pregnancy & Lactation:** There are no adequate data from the use of pregabalin in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Pregabalin should not be used during pregnancy unless clearly necessary. The effect of pregabalin on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue pregabalin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **Adverse Reactions:** Pregabalin: Anaphylactoid reaction such as decrease in blood pressure or dyspnea, may occur. The most commonly reported adverse reactions with pregabalin were dizziness and somnolence. Nortriptyline: most common hypotension, sedation, dry mouth, seizures, weight gain, gynecomastia in the male, and breast enlargement and galactorrhea in the female. Methylcobalamin: occasionally cause anorexia, nausea, vomiting, and diarrhea **Overdose:** No data are available about overdosage for FDC of Pregabalin (PR) 75 mg + Mecobalamin 1500 mcg + Nortriptyline 10 mg tablet in humans. FOR

FURTHER INFORMATION, PLEASE REFER FULL PRESCRIBING INFORMATION. Version date: 21st October 2022. If you require any further information, please reply us on productqueries@intaspharma.com.