Abridged Prescribing Information:

Active Ingredient: PREGABID CR 82.5 /165 mg extended release tablet contains Pregabalin 82.5 /165 mg

Indication: Treatment of peripheral neuropathic pain in adults. **Dosage & Administration:** For Treatment of Peripheral Neuropathic Pain Associated with Diabetic Peripheral Neuropathy: Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of is pregabalin extended release tablets 330 mg once daily. For Treatment of Peripheral Neuropathic Pain of Postherpetic Neuralgia: Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 330 mg once daily and who are able to tolerate pregabalin extended release tablets, may be treated with up to 660 mg once daily. The maximum recommended dose of pregabalin extended release tablets is 660 mg once daily. For conversion from pregabalin capsules or oral solution to pregabalin extended release tablets, please refer full prescribing information. **Contraindications:** Known hypersensitivity to product components. **Warnings & Precautions:** Angioedema, hypersensitivity reactions, suicidal behavior and ideation, peripheral edema, dizziness and somnolence, weight gain, risks associated with abrupt or rapid discontinuation, tumorigenic potential, creatine kinase elevations, decreased platelet count, PR interval prolongation. **Pregnancy & Lactation:** There are no adequate and well-controlled studies with pregabalin extended release tablets in pregnant women. Small amounts of pregabalin have been detected in the milk of lactating women. Based on animal studies, there is a potential risk of tumorigenicity with pregabalin exposure via breast milk to the breastfed infant. Hence breastfeeding is not recommended during treatment with Pregabalin extended release tablets. **Adverse Reactions:** Most common adverse reactions reported in greater than or equal to 4% of patients are dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain. **Overdose:** There is limited experience with overdose of pregabalin. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient. In the event of an overdose, it is reasonable to employ the usual supportive measures e.g. remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring (including obtaining an ECG) and institute supportive therapy if required. *(For details, please refer full prescribing information)*

Version date: 24 /02/20. If you require any further information, please reply us on productqueries@intaspharma.com