Abridged Prescribing Information:

Active Ingredient: PREGABID D capsules is a fixed-dose combination containing pregabalin + duloxetine (as delayed-release pallets): 75 mg + 20 mg/30 mg; 50 mg + 10mg/20 mg.

Indication: Treatment of peripheral neuropathic pain.

Dosage & Administration: one capsules to taken twice or thrice daily for relief of symptoms.

Contraindications: Known hypersensitivity to product components. Duloxetine: Concomitant use with non-selective, irreversible monoamine oxidase inhibitors (MAOIs); liver disease resulting in hepatic impairment; combination with fluvoxamine, ciprofloxacin or enoxacin (i.e. potent CYP1A2 inhibitors) as the combination results in elevated plasma concentrations of duloxetine Severe renal impairment (creatinine clearance <30 ml/min); patients with uncontrolled hypertension (may expose patients to a potential risk of hypertensive crisis).

Warnings & Precautions: Pregabalin: 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. Duloxetine: Mania and Seizures; Mydriasis: in patients with increased intraocular pressure or those at risk of acute narrow-angle glaucoma. Blood Pressure and Heart Rate: associated with an increase in blood pressure and clinically significant hypertension in some patients. Hepatic Impairment: Avoid use in patients with chronic liver disease or cirrhosis. Renal Impairment: Avoid use in patients with severe renal impairment, GFR <30 mL/minute.

Pregnancy & Lactation: Pregabalin: 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. Duloxetine: Pregnancy: Third trimester use may increase risk for symptoms of poor adaptation (respiratory distress, temperature instability, feeding difficulty, hypotonia, tremor, irritability) in the neonate. Lactation: Data from published literature report the presence of duloxetine in human milk. There are reports of sedation, poor feeding, and poor weight gain in infants exposed to duloxetine through breast milk. There are no data on the effect of duloxetine on milk production.

Adverse Reactions: Pregabalin: Most common adverse reactions are dizziness, somnolence, headache, fatigue, peripheral edema, nausea, blurred vision, dry mouth, and weight gain. Duloxetine: nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

Overdose: Pregabalin: 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. Duloxetine: Cases of overdoses, alone or in combination with other medicinal products, with duloxetine doses of 5400 mg were reported. Some fatalities have occurred, primarily with mixed overdoses, but also with duloxetine alone at a dose of approximately 1000 mg. Signs and symptoms of overdose (duloxetine alone or in combination with other medicinal products) included somnolence, coma, serotonin syndrome, seizures, vomiting and tachycardia. No specific antidote is known for duloxetine, but if serotonin syndrome ensues, specific treatment (such as with cyproheptadine and/or temperature control) may be considered. *(For details, please refer full prescribing information)*

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