PruLax™

Prucalopride

Presentation
PruLax™ Tablet: Each tablet contains Prucalopride Succinate INN equivalent to Prucalopride 2 mg.

Description
Prucalopride tablet contains Prucalopride succinate, a dihydrobenzofurancarboxamide that is a serotonin type 4 (5-HT4) receptor agonist.

Prucalopride is a gastrointestinal (GI) prokinetic agent that stimulates colonic peristalsis, which increases bowel motility. In isolated GI tissues from various animal species, Prucalopride facilitated acetylcholine release to enhance the amplitude of contractions and stimulate peristalsis.

Indication
Prucalopride is indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Dosage and Administration
Prucalopride can be taken with or without food. The recommended dosage is shown in below table:

Patients with CIC	Recommended Oral Dose
Adults	2 mg once daily

Renal Insufficiency: No dosage adjustment is required for patients with mild to moderate renal impairment. Prucalopride is known to be substantially excreted by the kidney. A decreased dosage is recommended in patients with severe renal impairment. Recommended dose in patients with severe renal impairment (creatinine clearance (CrCL) less than 30 mL/min) is 1 mg once daily.

Pediatric Use: Safety and effectiveness of Prucalopride in pediatric patients have not been established.

Geriatric Use: No overall differences in safety and effectiveness were observed in elderly patients.

Side effects
Headache, abdominal pain, nausea, vomiting, diarrhea, abdominal distension, dizziness, fatigue etc.

Contraindications
Prucalopride is contraindicated in patients with:
- A history of hypersensitivity to Prucalopride. Reactions including dyspnea, rash, pruritus and facial edema have been observed.
- During Intestinal perforation or obstruction, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum.

Use in Pregnancy and Lactation
Pregnancy: There is a limited amount of data from the use of Prucalopride in pregnant women. Prucalopride is not recommended during pregnancy and in women of childbearing potential planning to get pregnant.

Lactation: There are no data on the effects of Prucalopride on the breastfed child or the effects on milk production.

Drug interactions
No clinically significant differences in the pharmacokinetics of erythromycin, warfarin, digoxin, paroxetine, or oral contraceptives (ethinyl estradiol and norethisterone) were observed when co-administered with Prucalopride.

No clinically significant differences in Prucalopride pharmacokinetics was seen with co administration of Ketoconazole, Erythromycin, Probenecid, Cimetidine, or Paroxetine.

Overdose
Overdose symptoms includes headache, nausea, and diarrhea. Specific treatment is not available for Prucalopride overdose. In case of an overdose, treat symptomatically as required. Extensive fluid loss from diarrhea or vomiting may require correction of electrolyte disturbances.

Storage
Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack
PruLax™ Tablet: Each box contains 3 Alu-Alu blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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PRU V.N.01