Laxitab

Prucalopride

COMPOSITION

Laxitab 1 Tablet: Each film coated tablet contains Prucalopride Succinate INN equivalent to Prucalopride 1 mg.
Laxitab 2 Tablet: Each film coated tablet contains Prucalopride Succinate INN equivalent to Prucalopride 2 mg.

PHARMACOLOGY

Laxitab, a selective serotonin type-4 (5HT4) receptor agonist, is a gastrointestinal prokinetic agent that stimulates colonic peristalsis (High-Amplitude Propagated Contractions [HAPCs]), which increases bowel motility.

INDICATION

Laxitab is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

DOSAGE AND ADMINISTRATION

Adults: 2 mg once daily with or without food, at any time of the day.
Older people (>65 years): Start with 1 mg once daily, if needed the dose can be increased to 2 mg once daily.
Renal impairment: The dose for patients with severe renal impairment (GFR<30ml/min./1.73 m^2) is 1 mg once daily. No dose adjustment is required for patient with mild to moderate renal impairment.
Hepatic impairment: Patients with severe hepatic impairment (Child-Pugh class C) start with 1 mg once daily which may be increased to 2 mg if required to improve efficacy and if the 1 mg dose is well tolerated. No dose adjustment is required for patients with mild to moderate hepatic impairment.

Prucalopride should not be used in children and adolescents younger than 18 years.

CONTRAINDICATION

- Hypersensitivity to Prucalopride or to any of the ingredients of it.
- Renal impairment requiring dialysis.
- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon/megarectum.

WARNING AND PRECAUTION

Renal excretion is the main route of elimination of Prucalopride. A dose of 1 mg is recommended in severe renal impairment. Caution should be exercised when prescribing Prucalopride to patients with severe hepatic impairment (Child-Pugh class C). Caution should be exercised when prescribing to patients with severe and clinically unstable concomitant disease (e.g. cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders) especially when used in patients with a history of arrhythmias or ischaemic cardiovascular disease. In case of severe diarrhea, the efficacy of oral contraceptives may be reduced and the use of an additional contraceptive method is recommended to prevent possible failure of oral contraception. As this tablet contain lactose, patient with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

SIDE EFFECTS

The most frequently reported side effects associated with Laxitab therapy are headache and gastrointestinal symptoms (abdominal pain), nausea and diarrhea. The side effects occur predominantly at the start of therapy and usually disappear within a few days with continued treatment. The majority of adverse events were mild to moderate in intensity.

USE IN PREGNANCY & LACTATION

Prucalopride is not recommended during pregnancy and in women of childbearing potential not using contraception. It is not recommended to use Prucalopride during breast feeding.

DRUG INTERACTION

In-vitro data indicate that, Prucalopride has a low interaction potential and therapeutic concentrations of Prucalopride are not expected to affect the CYP-mediated metabolism of co-medicated medicinal products. Although Prucalopride may be a weak substrate for P-glycoprotein (P-gp), it is not an inhibitor of P-gp at clinically relevant concentrations. Ketoconazole (200 mg b.i.d), a potent inhibitor of CYP3A4 and of P-gp, increased the systemic exposure to Prucalopride by approximately 40%. Interactions of similar magnitude may be expected with other potent inhibitors of P-gp such as Verapamil, Cyclosporine A and Quinidine. Studies in healthy subjects showed that, there were no clinically relevant effects of Prucalopride on the pharmacokinetics of Warfarin, Digoxin, Alcohol, Paroxetine or oral contraceptives.

OVERDOSAGE

An overdose may result in symptoms include headache, nausea and diarrhea. In case of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbances.

STORAGE

Store below 30°C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Laxitab 1 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.
Laxitab 2 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.

02279/00

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.