Laxpru®

Prucalopride

COMPOSITION:

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

PHARMACOLOGY:

Prucalopride acts as a selective stimulator of the 5-HT4 receptors. While having no interaction with hERG channel or 5-HT1 receptors, which reduces significantly the cardiovascular risk found in other similar drugs. 5-HT4 receptors can be found throughout the gastrointestinal tract primarily in smooth muscle cells, enterochromaffin cells, and myenteric plexus. Its activation produces the release of acetylcholine which is the major excitatory neurotransmitter in the GI tract. Hence, prucalopride stimulates motility by interacting specifically with 5-HT4 receptors in the GI tract which causes a release of acetylcholine and further contraction of the muscle layer of the colon and relaxation of the circular muscle layer leading to the propulsion of luminal content.

INDICATION:

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

DOSE & ADMINISTRATION:

- Take with or without food.
- Recommended dosage by patient population:

Population with CIC	Recommended Oral Dose Regimen
Adult	2 mg once daily
Older People	1 mg daily (If needed dose increased 2 mg daily)
Patients with severe renal impairment (creatinine clearance (CrCL) less than 30 mL/min)	1 mg once daily

CONTRA-INDICATION:

Contraindicated to hypersensitivity of the active substance or to any of the excipients of Laxpru ® Tabet and people with 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 Laxpru ® Tablet. A dose of 1 mg is recommended in subjects with severe renal impairment.

Caution should be exercised when prescribing Laxpru ® Tablet to patients with severe hepatic impairment (Child-Pugh class C) due to limited data in patients with severe hepatic impairment. In case of severe diarrhoea, 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.

Laxpru ® Tablet contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

SIDE EFFECTS:

The most frequently reported adverse reactions associated with Laxpru ® Tablet therapy are headache (17.8%) and gastrointestinal symptoms (abdominal pain), nausea and diarrhoea. The adverse reactions occur predominantly at the start of therapy and usually disappear within a few days with continued treatment. Other adverse reactions have been reported occasionally. The majority of adverse events were mild to moderate in intensity.

USE IN PREGNANCY & LACTATION:

Laxpru ® Tablet is not recommended during pregnancy and women of childbearing potenial should use effective contraception during treatment. In animal studies do not indicate direct harmful effect with respect to pregnancy , embryonal/foetal development, parturition or postnatal development.

In the absence of human data, it is not recommended to use to Laxpru ® Tablet during breast feeding

USE IN CHILDREN & ADOLESCENTS:

Laxpru ® Tablet should not be used in children and adolescents younger than 18 years.

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%. This effect is too small to be clinically relevant. 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.

OVERDOSE:

An overdose may result in appearance of symptoms from an exaggeration of the known pharmacodynamic effects of Laxpru ® Tablet and includes headache, nausea, and diarrhea. Specific treatment is not available for Laxpru ® Tablet overdose. Should an overdose occur, treat symptomatically and institute supportive measures, as required. Extensive fluid loss from diarrhea or vomiting may require correction of electrolyte disturbances.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Laxpru ® 1 Tablet: Each box containing 3x10's tablets in Alu-PVDC blister pack.
Laxpru ® 2 Tablet: Each box containing 2x10's tablets in Alu-PVDC blister pack.

Manufactured by
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