SINAPRIDE

PRUCALOPRIDE

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

Pharmacology:
Prucalopride is a 5-HT4 receptor agonist. When 5-HT binds to these receptors, it normally stimulates movement in the gut. In the same way, when Prucalopride attaches to and stimulates these receptors, it increases this movement and allows the bowels to empty faster.

Dosage And Administration:
Chronic Constipation: Adults; 2 mg once daily with or without food, at any time of the day. Due to the specific mode of action of Prucalopride (stimulation of propulsive motility), exceeding the daily dose of 2 mg is not expected to increase efficacy. Older people; Start with 1 mg once daily; if needed the dose can be increased to 2 mg once daily. Children; Prucalopride should not be used in children and adolescents younger than 18 years. Renal Impairment: The dose for patients with severe renal impairment (GFR < 30 ml/ min/1.73 m2) is 1 mg once daily. No dose adjustment is required for patients 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.

Contraindications:
Prucalopride is contraindicated in those people who are hypersensitive to the active substance or to any of the excipients and people with renal impairment requiring dialysis.

Warning And Precaution:
Renal excretion is the main route of elimination of Prucalopride. A dose of 1 mg is recommended in subjects with severe renal impairment. Caution should be exercised when prescribing Prucalopride 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. The tablets 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 Prucalpride 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 and Lactation:
Prucalopride is not recommended during pregnancy and women of child bearing potential should use effective contraception during treatment. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/ fetal development, parturition or postnatal development. In the absence of human data, it is not recommended to use Prucalopride during breast feeding.

Drug Interaction:
Prucalopride has a low pharmacokinetic interaction potential. It is extensively excreted unchanged in urine (approximately 60% of the dose) and in vitro metabolism is very slow. A product that may interact with this drug is: pramlintide.

Overdosage:
An overdose may result in symptoms resulting from an exaggeration of prucalopride's known pharmacodynamic effects and include headache, nausea and diarrhoea. Specific treatment is not available for prucalopride overdose. if an overdose occur, the patient should be treated symptomatically and supportive measures instituted, as required. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Storage:
Keep in a cool (below 30°C) and dry place, protected from light. Keep out of the reach of children.

Packing:
Sinapride-1 tablet: Each box contains in 2x10 tablets in Alu-Alu blister pack. Sinapride-2 tablet: Each box contains in 2x10 tablets in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.