Caloprid™

Prucalopride

COMPOSITION

Caloprid™ **1** tablet: Each film coated tablet contains Prucalopride Succinate INN equivalent to Prucalopride 1 mg.

Caloprid™ **2** tablet: Each film coated tablet contains Prucalopride Succinate INN equivalent to Prucalopride 2 mg.

INDICATIONS AND USE

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

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.

WARNINGS

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 (Caloprid™) 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

ADVERSE REACTIONS

The most frequently reported adverse reactions associated with Caloprid™ 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.

DRUG INTERACTIONS

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.

USE IN PREGNANCY

Prucalopride is not recommended during pregnancy and women of childbearing potential should use effective contraception during treatment. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

USE IN LACTATION

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

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. Should 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

Store below 30^0C temperature, protected from light and moisture. Keep out of reach of children.

HOW SUPPLIED

Caloprid™ **1** tablet: Each box contains in 2x10's tablets in alu-alu blister pack.

Caloprid™ **2** tablet: Each box contains in 2x10's tablets in alu-alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Salgaria, Pabna, Bangladesh