PRUVICT LIQUID®

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for PRUVICT LIQUID [Prucalopride Oral Solution 0.2 mg/mL]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Prucalopride is a dihydrobenzofurancarboxamide with gastrointestinal prokinetic activities. Prucalopride is a selective, high affinity serotonin (5-HT4) receptor agonist, which is likely to explain its prokinetic effects. In vitro, only at concentrations exceeding its 5-HT4 receptor affinity by at least 150-fold, affinity for other receptors was detected. In rats, prucalopride in vivo, at doses above 5 mg/kg (at and above 30-70 times the clinical exposure), induced hyperprolactinaemia caused by an antagonistic action at the D2 receptor.

INDICATIONS: It is indicated for the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief.

DOSAGE AND ADMINISTRATION: 2 mg once daily (administered as 10 ml prucalopride oral solution) with or without food, at any time of the day. Paediatric population: Prucalopride should not be used in children and adolescents younger than 18 years.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, 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, and ulcerative colitis and toxic megacolon/megarectum.

WARNINGS & PRECAUTIONS: Renal excretion is the main route of elimination of prucalopride. A dose of 1 mg (administered as 5 ml prucalopride oral solution) is recommended in subjects with severe renal impairment. Caution should be exercised when prescribing prucalopride oral solution to patients with severe hepatic impairment (Child-Pugh class C) due to limited data in patients with severe hepatic impairment. There is limited information on the safety and efficacy of prucalopride for use in 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). Caution should be exercised when prescribing Prucalopride to patients with these conditions especially when used in patients with a history of arrhythmias or ischaemic cardiovascular disease. 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.

DRUG INTERACTIONS: Prucalopride has a low pharmacokinetic interaction potential. Prucalopride did not inhibit specific CYP450 activities in in vitro studies in human liver microsomes at therapeutically relevant concentrations. Although prucalopride may be a weak substrate for P-glycoprotein (P-gp), it is not an inhibitor of P-gp at clinically relevant concentrations A 30% increase in plasma concentrations of erythromycin was found during prucalopride co-administration. The mechanism for this interaction is not clear. Effects of other medicinal products on pharmacokinetics of prucalopride Ketoconazole (200 mg twice daily), 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.

ADVERSE REACTIONS: Decreased appetite, headache, dizziness, tremors, migraine, palpitations, vertigo, nausea, vomiting, diarrhea, abdominal pain, dyspepsia, flatulence, gastrointestinal sounds abnormal, rectal haemorrhage, pollakiuria, fatigue, pyrexia, malaise.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)