PRUVICT

For the use of a Registered Medical Practitioners or a Hospital or a Laboratory only Abbreviated prescribing information for **PRUVICT** [Prucalopride Tablets 1 mg / Prucalopride Tablets 2 mg] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: 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.

INDICATION: For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to Provide adequate relief.

DOSAGE AND ADMINISTRATION: 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. If the intake of once daily prucalopride is not effective after 4 weeks of treatment, the patient should be re-examined and the benefit of continuing treatment reconsidered.

CONTRAINDICATION: It is contraindicated in patients with hypersensitivity, renal impairment requiring dialysis and 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: Caution should be exercised when prescribing Prucalopride to patients with severe hepatic impairment (Child-Pugh class C) due to limited

Suicidal Ideation and Behavior

In reported clinical trials, suicides, suicide attempts, and suicidal ideation have been reported. A causal association between treatment with Prucalopride and an increased risk of suicidal ideation and behavior has not been established.

DRUG INTERACTIONS: Prucalopride interacts with erythromycin and ketoconazole.

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

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)