Prucalopride prescribing information sheet		
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Nottinghamshire Area Prescribing Committee

Prucalopride

Traffic light classification- Amber 2
Information sheet for Primary Care Prescribers

Licensed Indications

Prucalopride is recommended as an option for the treatment of chronic constipation only in patients for whom treatment with at least two laxatives from different classes, at the highest tolerated recommended doses for at least 6 months, has failed to provide adequate relief and invasive treatment for constipation is being considered.

Therapeutic Summary

Prucalopride (Resolor, Movetis) is a selective serotonin (5-HT4) receptor agonist that predominantly stimulates colonic motility. Prucalopride is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

Medicines Initiation

Prucalopride should only be prescribed by a clinician with experience of treating chronic constipation, who has carefully reviewed the woman's previous courses of laxative treatments in line with NICE guidance.
Such clinicians include specialist continence advisors within the community continence service.

Products available

Resolor 1mg and 2 mg film-coated tablets

Special precautions for storage

Store in the original blister in order to protect from moisture.

Dosages and route of administration

Prucalopride is taken orally.

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.

Special populations

Older people (>65 years): Start with 1 mg once daily; if needed the dose can be increased to 2 mg once daily.

Patients with 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.

Patients with 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.

Paediatric population: Prucalopride should not be used in children and adolescents younger than 18 years

Duration of treatment

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.

The efficacy of prucalopride has been established in double-blind, placebo-controlled studies for up to 3 months. Efficacy beyond three months has not been demonstrated in placebo-controlled studies. In case of prolonged treatment, the benefit should be reassessed at regular intervals.

Monitoring Requirements and Responsibilities

No monitoring is required; however efficacy will be reviewed after 4 weeks by the recommending clinician. Further review at 3 months will be completed to assess the risks and benefits of longer term treatment.
Following this the on-going need for the medication should be routinely reviewed by the prescribing GP.

Explicit criteria for review and discontinuation of the medicine

Contraindications

- 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.

Precautions

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.

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 (see the prescribing information of the oral contraceptive).

The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Women of childbearing potential

Women of childbearing potential have to use effective contraception during treatment with prucalopride

Pregnancy

Prucalopride is not recommended during pregnancy and in women of childbearing potential not using contraception.
There is a limited amount of data from the use of prucalopride in pregnant women. Cases of spontaneous abortion have been observed during clinical studies, although, in the presence of other risk factors, the relationship to prucalopride is unknown. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (including pregnancy, embryonal/foetal development, parturition or postnatal development).

Breast-feeding

A human study has shown that prucalopride is excreted in breast milk. At therapeutic doses no effects on breast-fed newborns/infants are anticipated. In the absence of human data in women who actively breast-fed while taking prucalopride, a decision should be made whether to discontinue breast-feeding or to discontinue therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

Animal studies indicate that there is no effect on male or female fertility.

Clinically relevant medicine interactions and their management

A 30% increase in plasma concentrations of erythromycin was found during prucalopride co-administration. The mechanism for this interaction is not clear.

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.

References

Resolor 1mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)