Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Prucalopride (Resolor®) – Advice for GPs when prescribed after consultation with Chronic Constipation Clinic

Please note this information is to assist in the management of patients of Sheffield Teaching Hospitals NHS Trust Chronic Constipation Clinic.
Summary of Product Characteristics (SPC) for prucalopride is available from www.medicines.org.uk and via National Institute for Health and Clinical Excellence (NICE) Technology Appraisals TA211 [NICE, 2010].
The licensed dose of prucalopride is 2mg once daily (in over 65yrs and in patients with severe hepatic impairment the initial dose is 1mg once daily, if needed the dose can be increased to 2 mg once daily; in severe renal impairment GFR < 30ml/min/1.73m^2 the dose is 1mg once daily).

What is prucalopride?
Prucalopride is a prokinetic 5HT-4 receptor agonist which stimulates gastrointestinal motility. Prucalopride is licensed for treatment of chronic constipation in adults.
NICE recommends that use of prucalopride is considered in patients who have been treated with two laxatives from different classes, at the highest tolerated dose for 6 months, and for whom invasive treatment (such as suppositories, enemas, rectal irrigation and/or manual disimpaction) in secondary care is being considered. Prucalopride is not a laxative and should be prescribed regularly.

Sheffield CCG recommends that prucalopride should not normally be initiated by primary care.
The NICE technical appraisal recommends that physicians initiating prucalopride should have experience in the management of chronic constipation, and have carefully reviewed the person's previous courses of laxative treatments.

How long should the initial trial be continued for and how is success defined?
Prucalopride should be tried initially for 4 weeks. If the patient reports either an improvement in symptoms or a reduction or discontinuation of laxative use, the treatment may be continued. GPs are asked to take over prescribing after trial is complete.

For how long should treatment be maintained?
If the initial trial is successful, it is recommended that treatment is **reviewed at 3 monthly intervals**.

It may be desirable to **consider a period without treatment after 6 months**. If constipation symptoms worsen or laxative use increases after stopping treatment, reintroduction of treatment according to SPC may be considered.

Laxative use whilst treated with prucalopride
Initially laxatives should be reduced or stopped. They may be reintroduced if treatment fails to provide satisfactory improvement in symptoms. Patients receiving large doses of macrogol (CosmoCol®) or Picolax® for rescue treatment should receive advice from the Chronic Constipation Clinic physician.

Precautions and initial adverse effects
Caution should be exercised when prescribing prucalopride to patients with severe and clinically unstable concomitant disease, 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.
Adverse effects are common when initiating treatment. The most frequently occurring reported for prucalopride are (frequency ≥ 1/10) headache and gastrointestinal symptoms (abdominal pain, nausea or diarrhoea). They most commonly subside within a few days with continued treatment. Patients are advised to continue treatment for 1 week before deciding whether they can tolerate minor adverse effects. Please see the manufacturer's SPC for advice regarding management of adverse reactions.

In what circumstances should a patient be re-referred to the clinic?
Please re-refer patients if they no longer respond to the treatment, despite treatment with the maximum licensed dose.

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