PRUCALOPRIDE FOR THE TREATMENT OF CHRONIC CONSTIPATION IN WOMEN

RECOMMENDED ONLY IN LINE WITH THE CRITERIA GIVEN

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<td>Prucalopride (Resolor®)</td>
<td>Serotonin (5-HT₄) receptor agonist</td>
<td>Treatment of chronic constipation in adult women</td>
<td>February 2011</td>
<td>Final</td>
<td>NICE – TA211, recommended</td>
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HMMC Recommendation, following further clarification of NICE TAG211 with specialists:

**RECOMMENDED FOR RESTRICTED USE** as a treatment Option in adult women with constipation in accordance with guidelines for the treatment of chronic constipation. Refer to attached guidelines.

Use only in patients who have not responded to treatment with at least one laxative from each of the main groups – bulk forming, osmotic, osmotic and stimulant, at maximum tolerated doses, over a period of at least 6 months.

NICE recommendation is that prucalopride is an option where the alternative would be consideration of invasive treatment for constipation. Therefore, use is strictly as a last line therapeutic option before referral.

**STOPPING criteria**

If there is no response to prucalopride after 28 days at a dose of 2mg/day, treatment should be stopped.

- Complete response is defined as more than 3 spontaneous complete bowel movements per week.
- Partial response is defined as at least 1 extra spontaneous complete bowel motion per week.

Non-responders may be referred to secondary care.

**NOT RECOMMENDED FOR:**

- Unlicensed indications
- Patients who have not been treated in accordance with the guidelines for management of chronic constipation

Guideline for the management of Chronic Constipation in Adults

(Not to be used in children <18yrs of age, or in pregnancy)

Over the last 6 month period:
<2 spontaneous complete bowel movements per week + one or more of the following:
  o Hard, lumpy stools
  o Sensation of incomplete evacuation
  o Straining during defecation

Yes

No response after at least 8 weeks at max tolerated dose
Ineffective after at least 8 weeks at max tolerated dose

Consider and address other causes:
Thyroid function, serum calcium, iatrogenic causes

Ineffective after 2-4 weeks

Add bulk forming agent, e.g., Ispaghula husk 1 bd and titrate up dose to effective/maximum tolerated dose.

Switch to/add in Osmotic laxative, +/- stool softener, e.g., lactulose 10ml bd, macrogol 1bd, docusate sodium 200mg od, titrate to effective/max tolerated dose.

Add in stimulant laxative, e.g., senna 1bd, and titrate to effective/max tolerated.

No response after at least 8 weeks at max tolerated dose

Female?

No response after at least 8 weeks at max tolerated dose.

>65 years
Prucalopride 1mg/day for 28 days

18-65 years
Prucalopride 2mg/day for 28 days

No response after 28 days

Red Flag constipation symptoms for immediate referral:
  o Palpable mass in lower right abdomen or the pelvis
  o Persistent rectal bleeding without anal symptoms
  o Unexplained weight loss, iron deficiency anaemia or nocturnal symptoms

Yes

Male?

No response after at least 8 weeks at max tolerated dose

Female?

No response after at least 8 weeks at max tolerated dose.

Doses shown are recommended starting doses, and should be titrated upwards to effective or maximum tolerated doses. Refer to BNF for doses, cautions and contra-indications. If a single agent fails, drugs from different groups should be used in combination to achieve optimum response.

Definition of complete response: ≥3 spontaneous complete bowel movements per week
Definition of partial response: an improvement of ≥ 1 spontaneous complete bowel movement per week

Note that prucalopride trials excluded patients where constipation was a result of endocrine, metabolic or neurological disorders, patients with renal or hepatic impairment or cardiovascular disease and those with drug induced constipation.