Prucalopride ▼(Resolor®)

Rationale for Initiation, Continuation and Discontinuation (RICaD)-

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

Rationale for Initiation. Continuation and Discontinuation

This document is recommended by the South Staffordshire Health Economy for drugs that have a "amber" classification in the "Joint Formulary", and are not subject to an ESCA, but for which extra guidance is felt to be needed. It is intended for completion by specialists in order to give Primary Care prescribers a clear indication of the reason for recommending the medication together with suggested criteria for its subsequent continuation or discontinuation. This RICaD should be provided as a supplement to the specialist's clinical letter.

PID		**Name**	
DOB		**Patient address**	

GP	**Dr**	**GP address**	

Rationale for Choice

The Interface Formulary for Adults states

	Specialists please complete all shaded areas as appropriate
Relevant Diagnosis:	Chronic constipation in women which has failed to respond to treatment with at least two laxatives from different classes at the highest tolerated recommended doses for at least six months. Invasive treatment for constipation is being considered.
Agreed Indication(s) for inclusion in the Interface Formulary:	Chronic constipation in women which has failed to respond to treatment with at least two laxatives from different classes at the highest tolerated recommended doses for at least six months. Invasive treatment for constipation is being considered. For specialist initiation in patients who would otherwise require one or more of the following: **Please check appropriate box** Stoma surgery ☐ Sacral neuromodulation ☐ Biofeedback ☐ Manual evacuation ☐ **Previous laxative treatments Please state specific treatments** Bulk forming: Stimulant: Faecal softeners: Osmotic laxatives:

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Reason why prucalopride has been chosen in preference to drugs without Formulary restrictions:	**Prucalopride is recommended by NICE as below**. 1. Prucalopride is an option for the treatment of chronic constipation only in women when treatment with at least two laxatives from different classes at the highest tolerated recommended doses for at least six months has failed to provide adequate relief and invasive treatment for constipation is being considered. **There is no equivalent formulary medicine available for use in this subgroup of women.**
Special precautions	• Caution in women with a history of arrhythmias or ischaemic cardiovascular disease. (Prucalopride belongs to the same class of drugs as cisapride, which is associated with serious cardiovascular side effects.Prucalopride has a selective mechanism of action and may not have the same cardiovascular side effects as cisapride. However, it is possible that,cardiovascular effects, may only be apparent after long-term treatment and were not observed in the clinical trials conducted.) • Patients should be instructed to report any onset of palpitations to their physician. • Temporarily patients should not drive or operate machinery if affected by dizziness or fatigue on starting treatment with prucalopride. • Resolor is not recommended during pregnancy. Women of childbearing potential should use effective contraception during treatment with prucalopride. In case of severe diarrhoea, the efficacy of oral contraceptives may be reduced and an additional contraceptive method is recommended.
Pre-treatment test results	**Please complete findings** Baseline ECG Liver function Renal function
Specialist name **(please print)**	

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Contact details	
Signature	
Date	

Guidance on initiation

Initiation dose:	*Women*: 2 mg prucalopride once daily. (Doses over 2 mg daily are not expected to increase efficacy) *Elderly (>65 years)*: 1 mg once daily initially; increased to 2 mg once daily if needed. In severe renal impairment (GFR < 30 ml/min/1.73 m^2) 1 mg once daily In severe hepatic impairment (Child-Pugh class C) 1 mg once daily
Additional info:	SPC can be accessed at http://emc.medicines.org.uk
Monitoring:	No specific/ mandatory monitoring required

Suggested Criteria for Continuation or Discontinuation

Assessment of Efficacy	
Frequency	**Clinical review in OPD at 4 weeks** to assess potential benefit of treatment and consider continuation or discontinuation of prucalopride.
Location	
Method	Routine outpatient clinical review
Continuation Criteria	If treatment continues to be effective and tolerated by the patient.

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Discontinuation Criteria	If treatment ceases to be effective.
Follow up action	There is no requirement for specific follow up.