

## **PRESS RELEASE**

### **NICE recommends prucalopride for chronic constipation in women**

In final guidance published today (15 December 2010), NICE recommends prucalopride (Resolor, Movetis) as a treatment option for some women with chronic constipation in whom laxatives have not provided adequate relief.

The guidance recommends that prucalopride<sup>1</sup> should only be considered in women:

- who have tried at least two different types of laxatives from different classes (at the highest tolerated recommended doses) for at least six months, but have not had relief from constipation, and
- in whom invasive treatment is being considered.

Prucalopride should only be prescribed by a clinician with experience of treating chronic constipation, and who has reviewed the woman's previous course of laxatives. If treatment with prucalopride is not effective after four weeks, the benefit of continuing treatment should be reconsidered.

Constipation, which can be caused by dietary changes, stress or immobility, is defined as passing abnormally delayed or infrequent dry, hardened faeces (stools), often accompanied by straining and/or pain. People with chronic constipation have no more than two spontaneous complete bowel movements per week.

Constipation may also be the consequence of an underlying condition, including irritable bowel syndrome, or an underactive thyroid. In addition, some medications

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<sup>1</sup> Prucalopride stimulates colonic activity and movement.

cause constipation as a side effect. These include opioids (e.g. common codeine pain killers) and diuretics<sup>2</sup>. Chronic constipation affects on average two to three times as many women as men, with prevalence rates of around 10% in women under 65 years of age in the UK. Rates are often higher (around 20%) in women over 65 years of age.

Appropriate diet and lifestyle changes should be the first step in managing constipation. If this is unsuccessful, laxatives may relieve the symptoms and restore normal bowel function. Prucalopride can be prescribed for women with long term constipation, whose condition has not responded to standard laxatives.

**Professor Peter Littlejohns, Clinical and Public Health Director at NICE**

**said:** “Chronic constipation, although not life-threatening, can have a significant effect on quality of life, often accompanied by a host of unpleasant symptoms, like irritability, lethargy and painful bloating. We are pleased, therefore, to be able to recommend prucalopride as a clinically and cost effective treatment for some women whose chronic constipation has not been managed with standard laxatives.”

The final guidance can be found at

<http://guidance.nice.org.uk/TA211>

This is NICE’s final guidance on this technology. Once NICE issues its final guidance it replaces local recommendations across the country.

**Ends.**

**Notes to Editors**

**About the appraisal**

- The guidance can be found at <http://guidance.nice.org.uk/TA211>
- Through the data presented, prucalopride was shown to be clinically and cost effective in providing relief to women with laxative-refractory chronic constipation.
- The costs of managing chronic constipation in laxative-refractory patients included in the information presented (such as referrals to secondary care, rectal irrigation and surgery), could also be reduced by the use of prucalopride.
- Prucalopride is administered orally. The summary of product characteristics (SPC) states that the recommended dose of prucalopride is 2 mg once daily for adult women (up to 65

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<sup>2</sup> A diuretic is any drug that increases the rate of urination.

years old), and 1 mg once daily for older women (over 65 years old). The dose for older women can be increased to 2 mg once daily if needed. If the intake of once daily prucalopride is not effective after four weeks, the patient should be re-examined and the benefit of continuing treatment reconsidered.

- The SPC reports that the most common adverse effects that may be associated with prucalopride treatment include headache and gastrointestinal symptoms (abdominal pain, nausea or diarrhoea). Most adverse effects occur at the start of treatment and usually subside within a few days of continued treatment.
- Prucalopride is available in 1mg and 2mg tablets. The acquisition cost of prucalopride 1 mg is £38.69 for a pack of 28 tablets. The acquisition cost of prucalopride 2mg is £59.52 for a pack of 28 tablets (excluding VAT; British National Formulary [BNF], 60th edition). The manufacturer estimated that the annual cost of treatment with prucalopride is £622.00 for adult women and £403.00 for older women, excluding any monitoring costs, assuming that each patient receives treatment for an average of 220 days each year. Costs may vary in different settings because of negotiated procurement discounts.
- Prucalopride has not been tested in enough men to show that it works for them, so should only be prescribed for women.

## About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance and standards on the promotion of good health and the prevention and treatment of ill health.

2. NICE produces guidance in three areas of health:

- **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
- **health technologies** – guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
- **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

3. NICE produces standards for patient care:

- **quality standards** – these reflect the very best in high quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services
- **Quality and Outcomes Framework** – NICE develops the clinical and health improvement indicators in the QOF, the Department of Health scheme which rewards GPs for how well they care for patients.

4. NICE provides advice and support on putting NICE guidance and standards into practice through its **implementation programme**, and it collates and accredits high quality health guidance, research and information to help health professionals deliver the best patient care through **NHS Evidence**.