



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/337043/2015  
EMA/H/C/001012

## EPAR summary for the public

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# Resolor

prucalopride

This is a summary of the European public assessment report (EPAR) for Resolor. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Resolor.

### What is Resolor?

Resolor is a medicine that contains the active substance prucalopride. It is available as tablets (1 and 2 mg).

### What is Resolor used for?

Resolor is used to treat symptoms of chronic (long-term) constipation in adults for whom laxatives (medicines that trigger bowel movements) do not work well enough.

The medicine can only be obtained with a prescription.

### How is Resolor used?

The recommended dose of Resolor is 2 mg taken once a day. Patients aged over 65 years should start with a 1 mg dose once a day, and this can be increased to 2 mg once a day if needed.

### How does Resolor work?

The active substance in Resolor, prucalopride, is a '5-HT<sub>4</sub> receptor agonist'. This means that it works like a substance in the body called 5-hydroxytryptamine (5-HT, also known as serotonin) and attaches to receptors for 5-HT in the gut called '5-HT<sub>4</sub> receptors'.



When 5-HT binds to these receptors, it normally stimulates movement in the gut. In the same way, when prucalopride attaches to and stimulates these receptors, it increases this movement and allows the bowels to empty faster.

### **How has Resolor been studied?**

Resolor (2 or 4 mg once a day) was compared with placebo (a dummy treatment) in three main studies involving 1,999 patients with chronic constipation, 88% of whom were women. The patients had not responded well enough to previous treatment with laxatives.

Resolor 2 mg once a day was also compared with placebo in another main study involving 374 men with chronic constipation.

The main measure of effectiveness in the studies was the number of patients who completely emptied their bowels at least three times a week over a 12 week period without the help of laxatives.

### **What benefit has Resolor shown during the studies?**

Resolor was more effective than placebo at treating chronic constipation. Over the 12-week period, 24% (151 out of 640) of patients who received Resolor 2 mg completely emptied their bowels at least three times a week, compared with 11% (73 out of 645) of patients who received placebo. The result from patients who received Resolor at the higher dose of 4 mg was similar to those who took the 2 mg dose.

In the study of men with chronic constipation, 38% of patients treated with Resolor 2 mg (67 out of 177) completely emptied their bowels at least three times a week, compared with 18% of those given placebo (32 out of 181).

### **What is the risk associated with Resolor?**

The most common side effects with Resolor (seen in more than 1 patient in 10) are headache, nausea (feeling sick), diarrhoea and abdominal (tummy) pain. For the full list of all side effects reported with Resolor, see the package leaflet.

Resolor must not be used in patients with kidney problems requiring dialysis (a blood clearance technique). It must also not be used in patients with intestinal perforation or obstruction, severe inflammatory conditions of the intestines such as Crohn's disease, ulcerative colitis (inflammation of the large intestine causing ulceration and bleeding) and toxic megacolon and megarectum (very serious complications of colitis). For the full list of restrictions, see the package leaflet.

### **Why has Resolor been approved?**

The CHMP decided that Resolor's benefits are greater than its risks and recommended that it be given marketing authorisation..

### **What measures are being taken to ensure the safe and effective use of Resolor?**

A risk management plan has been developed to ensure that Resolor is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Resolor, including the appropriate precautions to be followed by healthcare professionals and patients.

### **Other information about Resolor**

The European Commission granted a marketing authorisation valid throughout the European Union for Resolor on 15 October 2009.

The full EPAR for Resolor can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Resolor, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2015.