

### **Prescribing Information (UK)**

(Please refer to the full Summary of Product Characteristics before prescribing.)

#### **RESOLOR® ▼**(prucalopride)

Selective serotonin (5-HT<sub>4</sub>) receptor agonist, enterokinetic agent, available as 1 mg and 2 mg film-coated tablets for oral administration, once daily, with or without food, at any time of the day. **Indication:** Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. **Dose:** Women: 2 mg once daily, elderly (> 65 years): Start with 1 mg once daily and increase to 2 mg once daily if necessary. Patients with severe renal impairment (GFR < 30 ml/min/1.73m<sup>2</sup>): 1 mg once daily. Patients with severe hepatic impairment (Child-Pugh class C): 1 mg once daily. No dose adjustment required in patients with mild to moderate renal or hepatic impairment. Men, children and adolescents <18 years: not recommended until further data become available. **Contraindications:** Hypersensitivity to prucalopride or any of the excipients. Renal impairment requiring dialysis. Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease, and ulcerative colitis and toxic megacolon/megarectum. **Precautions:** Patients with severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders) have not been studied. Caution should be exercised when prescribing Resolor to patients with these conditions. In particular Resolor should be used with caution 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 an additional contraceptive method is recommended. Contains lactose monohydrate. Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption must not take Resolor. **Interactions:** Prucalopride has a low potential for drug interactions. Studies in healthy subjects did not show a clinically relevant effect of prucalopride on the pharmacokinetics of warfarin, digoxin, alcohol or paroxetine. There was a 30% increase in plasma concentrations of erythromycin on coadministration with prucalopride. This was more likely to be related to a high intrinsic variability in erythromycin kinetics rather than due to an effect of prucalopride. Ketoconazole increased prucalopride bioavailability by 40% possibly via inhibition of P-gp-mediated renal transport. This effect is thought too small to be clinically relevant. Therapeutic doses of probenecid, cimetidine, erythromycin and paroxetine did not affect the pharmacokinetics of prucalopride. Use with caution in patients receiving concomitant drugs known to cause QTc prolongation. Atropine-like substances may reduce the 5-HT<sub>4</sub>-mediated effects of prucalopride. **Pregnancy:** Animal studies did not indicate harm. Experience of Resolor during human pregnancy is limited. Cases of spontaneous abortion have been observed in human clinical studies although, in the presence of other risk factors, the relationship to Resolor is unknown. Resolor is not recommended during pregnancy. Women of childbearing potential should use effective contraception during treatment with Resolor. **Lactation:** Prucalopride is excreted in breast milk, however at therapeutic doses no effects are anticipated on the breastfed newborn/infant. In the absence of human data Resolor is not recommended during breastfeeding. **Effects on ability to drive and use machines:** No studies have been performed. Resolor has been associated with dizziness and fatigue, particularly on the first day of treatment, which may affect driving or using machines. **Side effects:** The most commonly reported side effects in Resolor clinical trials were headache and gastrointestinal symptoms (abdominal pain, nausea, diarrhoea) occurring in about 20% of patients each. These events occur mostly at the start of therapy and usually disappear within a few days whilst continuing Resolor. Other common adverse events in controlled trials included dizziness, vomiting, dyspepsia, rectal haemorrhage, flatulence, abnormal bowel sounds, pollakiuria and fatigue. Uncommon adverse events included anorexia, tremors, palpitations, fever and malaise. After the first day of treatment the most common adverse events were reported with similar frequency for Resolor and placebo except nausea and diarrhoea: these remained higher but the difference between Resolor and placebo was smaller (1 to 3%). Palpitations were reported in 0.7% of placebo patients, 1.0% of 1 mg Resolor patients and 0.7% of 2 mg Resolor patients. As with any new symptom, patients are advised to discuss new onset palpitations with their physician. **Pack size and basic NHS prices:** 28 tablets (4 blisters with 7 tablets) EU/1/09/581/001 (1 mg) £38.69, EU/1/09/581/002 (2 mg) £59.52. **Legal category:** POM **Marketing Authorisation Holder:** Shire-Movetis N.V., Veedijk 58 (1004), 2300 Turnhout, Belgium. **Date of preparation:** December 2010.

**Adverse events should be reported. Reporting forms and information can be found at**  
[www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). **Adverse events should also be reported to Shire on 01256 894000**