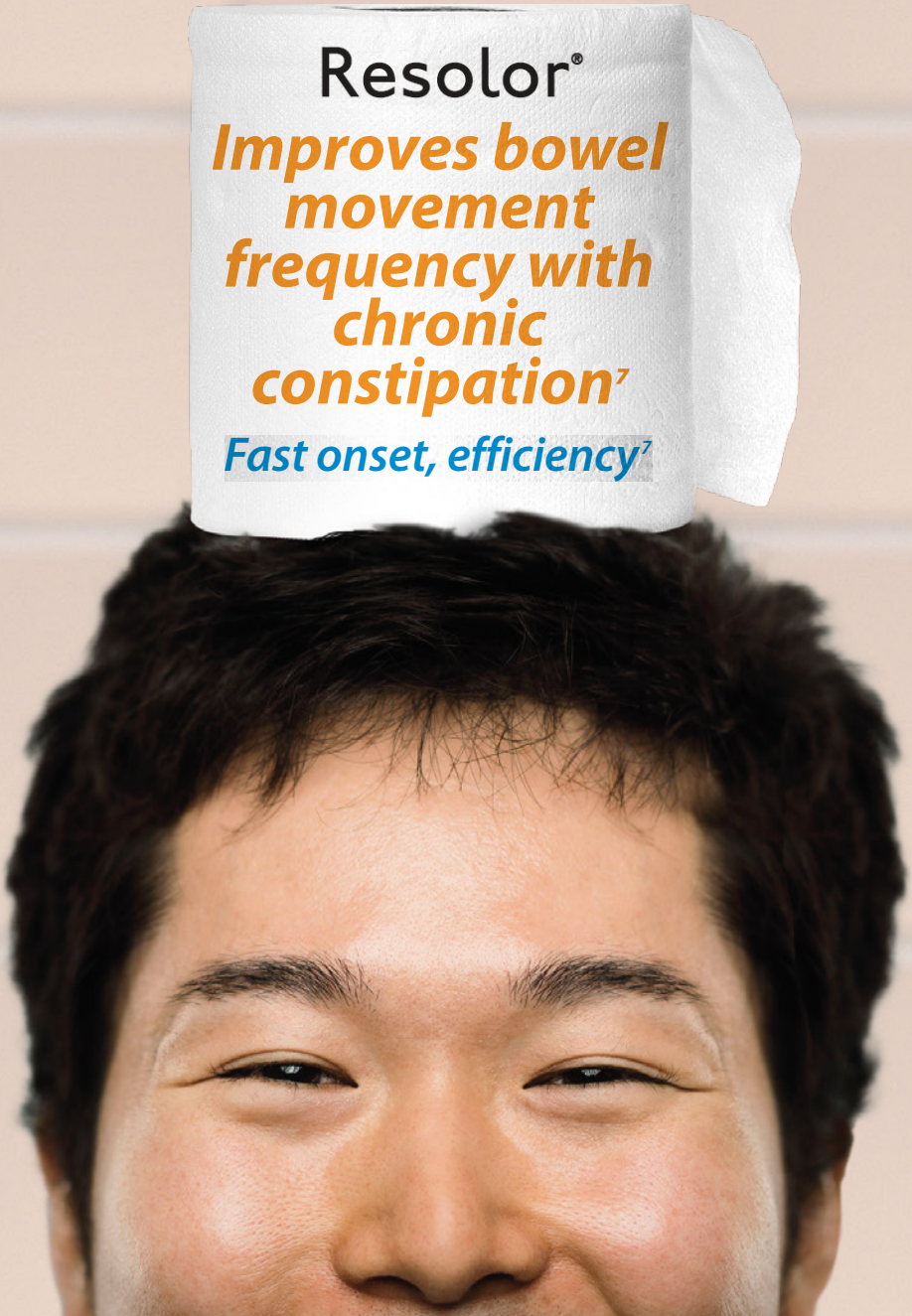
For sales distribution to HCPs



Resolor® 2mg significantly improves bowel function[1-4]

First SCBM# could be achieved within a median of 1.3 days, compared to patients on placebo who required 12.6 days[1]

30.9% of patients taking prucalopride achieve mean of ≥ 3 SCBM/ week compared to 12% in placebo over 12 weeks[1]

6 in 10 patients achieved increase of ≥ 1 SBM per week[1]*

* SBM = Spontaneous bowel movement

\# SCBM = Spontaneous complete bowel movement

66.7% of patients[1]
Increase of ≥ 1 SBM* per week

43.5% of patients[1]
Increase of ≥ 1 SCBM# per week

Efficacy and Safety of Prucalopride in Chronic Constipation[5]

Patients with mean frequency of ≥3 SCBM/week

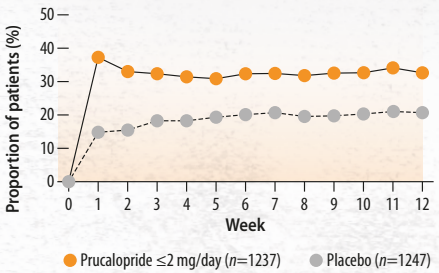


Fig. 1 Proportion of patients in the pooled population with a mean frequency of ≥3 spontaneous complete bowel movements/week over the 12-week treatment period, by individual weekly period

Women and men with mean frequency of ≥3 SCBM/week

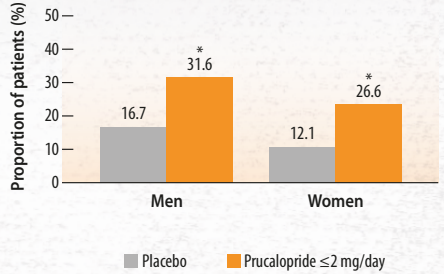


Fig. 2 Proportion of patients in the pooled population with a mean frequency of ≥3 spontaneous complete bowel movements per week over the 1-12 week treatment period analyzed by sex. *p < 0.001 versus placebo

Women and men with mean frequency of ≥3 SCBM/week analyzed by individual weekly period

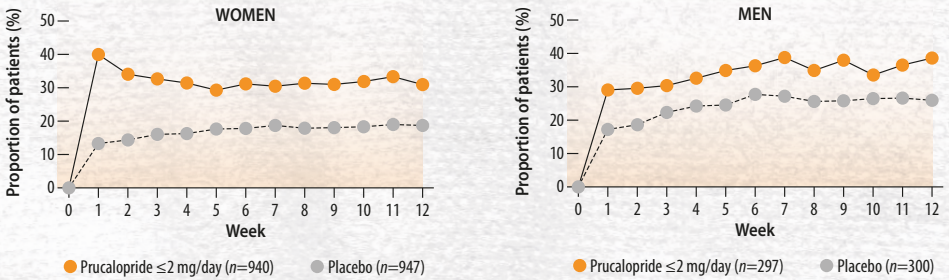


Fig. 3 Proportion of women and men in the pooled population with a mean frequency of ≥3 spontaneous complete bowel movements per week over the 12-week treatment period analyzed by individual weekly period

Study designs: All trials included adult patients with CC [defined as B2 spontaneous bowel movements (SBMs) per week for at least 6 months]. In addition, participants had to have hard or very hard stools, a sensation of incomplete evacuation, or straining during defecation in at least 25 % of bowel movements (BMs). Patients were excluded if they were considered to have drug-induced constipation, or constipation secondary to causes such as endocrine, metabolic, or neurological disorders, or surgery. The doses of prucalopride used in the trials varied from 1 to 4 mg/day; the approved 2 mg/day dose was evaluated in all of the trials (Table 1). Only patients receiving prucalopride 2 mg/day and the few individuals who received prucalopride 1 mg/day throughout a trial were included in this integrated analysis.

Resolor® provides convenient, once-daily dosing[1]

- Once daily dosing taken at any time of the day[6]
- Can be taken with or without food[6]
- Fast onset of action: median of 2.5 hours to first SBM[7]
- Most adverse events were mild or moderate in severity and occurred primarily during the first day of treatment[1]

Dosage

Adults

film-coated tablets

Older people (>65 years)

film-coated tablets

Start with 1 mg once daily (see section 5.2); if needed the dose can be increased to 2 mg once daily.

Patients with renal impairment

film-coated tablets

The dose for patients with severe renal impairment (GFR < 30ml/min/ 1.73 m2) is 1 mg once daily. No dose adjustment is required for patients with mild to moderate renal impairment.

Patients with hepatic impairment

film-coated tablets

Patients with severe hepatic impairment (Child-Pugh class C) start with 1 mg once daily which may be increased to 2 mg if required to improve efficacy and if the 1 mg dose is well tolerated. No dose adjustment is required for patients with mild to moderate hepatic impairment.

RESOLOR® ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Prucalopride **INDICATION(S):** For symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief. **DOSAGE & ADMINISTRATION:** Adults: 2 mg once daily with or without food, at any time of the day. If the intake of once daily prucalopride is not effective after 4 weeks of treatment, the patient should be re-examined and the benefit of continuing treatment reconsidered. Older people (>65 years): Start with 1 mg once daily; dose can be increased to 2 mg once daily if needed. Patients with severe renal impairment (GFR < 30 ml/min/1.73 m²): 1 mg once daily. Patients with severe hepatic impairment (Child-Pugh class C): start with 1 mg once daily which may be increased to 2 mg if required and if the 1 mg dose is well tolerated. No dose adjustment is required for patients with mild to moderate renal / hepatic impairment. Oral use. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to 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. **SPECIAL WARNINGS & PRECAUTIONS:** Caution should be exercised when prescribing Resolor to patients with severe hepatic impairment (Child-Pugh class C), patients with history of arrhythmias or ischaemic cardiovascular disease. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Resolor. **SIDE EFFECTS:** Headache, gastrointestinal symptoms including abdominal pain, nausea and diarrhoea. Refer to the full prescribing information for other side effects. **PREGNANCY & LACTATION:** Women of childbearing potential have to use effective contraception during treatment with prucalopride. Resolor is not recommended during pregnancy and in women of childbearing potential not using contraception. Decision should be made whether to discontinue breast feeding or to discontinue Resolor therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. **INTERACTIONS:** Prucalopride has a low pharmacokinetic interaction potential. **PLEASE REFER TO FULL PRESCRIBING INFORMATION BEFORE PRESCRIBING.** API version to be quoted on promotional material: Resolor aPI ver.1.0

References: 1. Camilleri M et al, N Engl J Med 2008; 358:2344-54 **2.** ke M Y Tack J et al, Neurogastroenterol Motil. 2012; 24[11]:999-e541 **3.** Yiannakou Y et al, Am J Gastroenterol. 2015; 110[5]:741-748 **4.** Tack J et al, United European Gastroenterol J. 2013; 1 {1]: 48-59 **5.** Camilleri M et al, Dig Dis Sci 2016; 61:2357-2372 **6.** Resolor® Hong Kong Prescribing Information P05 **7.** Johanson JF et al, Gastroenterology 2000; 118:A175

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