prucalopride (Resolor®) and chronic constipation in men

Avoid in both men and women

● In a placebo-controlled trial in 374 men, prucalopride was only effective in a minority of cases, as previously observed in women. In addition to its cardiovascular harms, there is evidence that prucalopride may cause depression and suicidal ideation.

Possible depression and suicidal ideation, in addition to cardiovascular harms. The adverse effect profile of prucalopride mainly includes cardiovascular disorders (palpitations, ischaemic cardiovascular events, possible QT prolongation), gastrointestinal disorders (nausea, diarrhoea, abdominal pain), headache and dizziness.

In the trial in men, gastrointestinal disorders and headache were more frequent in the prucalopride group (3,4). The frequency of cardiac disorders was similar in the two groups, but it should be noted that patients with a history of cardiovascular disease were excluded from the trial (4). In France, a 3-year post-marketing study identified 7 cases of palpitations and tachycardia in patients taking prucalopride (6). As part of the risk management plan, a study is underway in the UK to better document cardiovascular adverse effects (3).

During the trial, depression occurred in two men in the prucalopride group and none in the placebo group (4). The Uppsala pharmacovigilance centre of the World Health Organization (WHO) has reported 3 cases of suicidal ideation among prucalopride-treated patients with no history of psychiatric disorders, with a favourable outcome after drug withdrawal. This adverse effect has also been reported with tegaserod, another 5HT4 agonist that was authorised to treat constipation in some countries, before it was withdrawn from the market (7).

In practice. For men presenting with constipation, a troublesome but usually benign disorder, prucalopride carries a disproportionate risk of cardiovascular disorders, depression and suicidal ideation. As in women, it is better to optimise the use of standard laxatives, and to avoid prucalopride altogether.

prucalopride tablets
Resolor®
• 1 mg or 2 mg of prucalopride per tablet

laxative; serotonin 5-HT4 agonist

New indication: "(...) symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief."

[EU centralised authorisation]


Selected references from Prescrire’s literature search.

- ANSM “Réunion du comité technique de pharmacovigilance - CT012015043” 17 April 2015: 16 pages.