

Part VI: Summary of the risk management plan

Summary of risk management plan for Prucalopride 1 mg and 2 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Prucalopride 1 mg and 2 mg film-coated tablets.

The RMP details important risks of Prucalopride 1 mg and 2 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Prucalopride 1 mg and 2 mg film-coated tablet's risks and uncertainties (missing information).

Prucalopride 1 mg and 2 mg film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prucalopride 1 mg and 2 mg film-coated tablets should be used.

I. The medicine and what it is used for

Prucalopride 1 mg and 2 mg film-coated tablets are authorised for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief (see SmPC for the full indication).

It contains Prucalopride as the active substance and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Prucalopride 1 mg and 2 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Prucalopride 1 mg and 2 mg film-coated tablets's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Prucalopride 1 mg and 2 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Prucalopride 1 mg and 2 mg film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that

the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Prucalopride 1 mg and 2 mg film-coated tablets. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> • Palpitations
Important potential risks	<ul style="list-style-type: none"> • Cardiovascular and cerebrovascular ischaemic events • Ischaemic colitis • QT prolongation, and related ventricular events and syncope
Missing information	<ul style="list-style-type: none"> • Safety in pregnant women • Safety in patients with severe hepatic impairment • Safety in patients with severe and unstable cardiovascular disease

The above stated list of safety concerns are obtained from the approved Risk Management Plan (RMP) latest version 13.0 of reference product Resolor (Prucalopride).

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Prucalopride 1 mg and 2 mg film-coated tablets

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Prucalopride 1 mg and 2 mg film-coated tablets.