Part VI: Summary of the risk management plan

Summary of risk management plan for Prucalopride 1 mg & 2 mg Film coated Tablets.

This is a summary of the risk management plan (RMP) for Prucalopride. The RMP details important risks of Prucalopride, how these risks can be minimised and how more information will be obtained about Prucalopride's risks and uncertainties (missing information).

Prucalopride's summary of product characteristics gives essential information to healthcare professionals and patients on how Prucalopride's should be used.

Important new concerns or changes to the current ones will be included in updates of Prucalopride's RMP.

I. The medicine and what it is used for

Prucalopride is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

It contains Prucalopride as the active substance and it is given by orally.

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

Important risks of Prucalopride, together with measures to minimise such risks and learning more about Prucalopride'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 leaflets 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Prucalopride is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Prucalopride are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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. 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	Palpitations
Important potential risks	Cardiovascular and cerebrovascular ischaemic events
	Ischaemic colitis
	QT prolongation, and related ventricular events and syncope
Missing information	Safety in pregnant women
	Safety in patients with severe hepatic impairment
	Safety in patients with severe and unstable cardiovascular disease

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

No post-authorisation study is planned for this product.

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.

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

There are no studies required for Prucalopride.