Part VI: Summary of the risk management plan

Summary of risk management plan for for Prucalopride film-coated tablets (prucalopride)

This is a summary of the risk management plan (RMP) for Prucalopride film-coated tablets. The RMP details important risks of Prucalopride film-coated tablets, 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 (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prucalopride film-coated tablets 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 film-coated tablets are authorised for the treatment of chronic constipation in adults in whom laxatives do not work well enough (see SmPC for the full indication). It contains prucalopride as the active substance and it is given by mouth. Prucalopride is available as film-coated tablet in strengths of 1 mg and 2 mg.

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 the proposed studies for 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 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 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 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. 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 ischaernic 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

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.