Part VI: Summary of the risk management plan for Prucalopride Orifarm

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

Prucalopride Orifarm's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prucalopride Orifarm should be used.

I. The medicine and what it is used for

Prucalopride Orifarm is authorised for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief. It contains prucalopride as the active substances and it is given as a film-coated tablet.

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

Important risks of Prucalopride Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Prucalopride Orifarm's risks, are outlined below.

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish, Swedish, Norwegian and Finnish Medicines Agency.
- The medicine's is prescription only medicine and must be prescribed by a doctor.

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

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

II.A List of important risks and missing information

Important risks of Prucalopride Orifarm 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 Orifarm. 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);

Summary of safety concerns	
Important identified risks	• Palpitations
Important potential risks	• Cardiovascular and cerebrovascular ischaemic events • Ischaemic colitis • QT prolongation, related ventricular arrhythmias, 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 Orifarm.

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

There are no studies required for Prucalopride Orifarm.