SUMMARY OF THE RISK MANAGEMENT PLAN for Prucalopride SanoSwiss film-coated tablets (Prucalopride)

This is a summary of the risk management plan for Prucalopride SanoSwiss film-coated tablets. The RMP details important risks of Prucalopride SanoSwiss film-coated tablets and how these risks can be minimised.

Prucalopride SanoSwiss film-coated tablets summary of product characteristics and its package leaflet give essential information to healthcare professionals and patients on how Prucalopride SanoSwiss film-coated tablets should be used.

I. The medicine and what is used for

Prucalopride SanoSwiss film-coated tablets is authorised 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 1 mg or 2 mg film-coated tablets orally.

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

Important risks of Prucalopride SanoSwiss film-coated tablets, together with measures to minimise such 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;
- The medicine´s legal status - the way a medicine is supplied to the patient (only with medical prescription) can help to minimise the risks.

Together, these measures constitute routine risk minimisation measures.

If important information that may affect the safe use of Prucalopride SanoSwiss 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 SanoSwiss 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 SanoSwiss 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 yet 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.

Summary of safety concerns	
Important identified risks	- Palpitations
Important potential risks	- Cardiovascular and cerebrovascular ischemic events - QT prolongation, and related ventricular events and syncope - Ischemic colitis
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 conditions of the marketing authorisation or specific obligation of Prucalopride SanoSwiss film-coated tablets.

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

There are no studies required for Prucalopride SanoSwiss film-coated tablets.