Part VI: Summary of the risk management plan

Summary of risk management plan for RosufenX (rosuvastatin/ fenofibrate)

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

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

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

I. The medicine and what it is used for

RosufenX is authorised as substitution therapy adjunctive to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) for the treatment of mixed hyperlipidaemia in adult patients at high cardiovascular risk who are adequately controlled with rosuvastatin and fenofibrate given concurrently at same dose level as in the fixed dose combination, but as separate products. It contains rosuvastatin and fenofibrate as the active substances and it is given by oral route.

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

Important risks of RosufenX, together with measures to minimise such risks and the proposed studies for learning more about RosufenX, 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.

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

II.A List of important risks and missing information

Important risks of RosufenX 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 RosufenX. 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	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the current Product Information is aligned to the reference medicinal products.

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 RosufenX.

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

There are no studies required for RosufenX.