Part VI: Summary of the risk management plan

Summary of risk management plan for ROXAM (rosuvastatin (as rosuvastatin calcium) and amlodipine (as amlodipine besylate))

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

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

I. The medicine and what it is used for

Rosuvastatin and amlodipine fixed dose combination is indicated as substitution therapy for those patients who are adequately controlled with rosuvastatin and amlodipine given concurrently, at the same dose level as in the combination. The medicinal product is indicated for the treatment of hypertension in adult patients who are estimated to have a high risk for a first cardiovascular event (for prevention of major cardiovascular events) as an adjunct to correction of other risk factors or with one of the following coincident conditions:

- primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate

- homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate (see SmPC for the full indication).

It contains rosuvastatin and amlodipine as the active substances and it is given orally.

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

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

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 ROXAM 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 ROXAM. 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 proposed product information is aligned to the latest knowledge about the monocomponents of 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 ROXAM.

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

There are no studies required for ROXAM.