Part VI: Summary of the risk management plan

Summary of risk management plan for Rosuvastatin Aurobindo 5 mg, 10 mg, 20 mg and 40 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Rosuvastatin Aurobindo 5 mg, 10 mg, 20 mg and 40 mg film-coated tablets (hereinafter referred to as Rosuvastatin). Rosuvastatin is a well-known product and safety concerns are sufficiently addressed in the product information. Hence, risks are considered not important for the inclusion in the RMP.

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

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

I. The medicine and what it is used for

Rosuvastatin Aurobindo is used in adults, adolescents and children 6 years or older to treat high cholesterol. (SmPC for the full indication). It contains rosuvastatin as the active substance and is given orally.

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

Important risks of rosuvastatin, together with measures to minimise such risks and the proposed studies for learning more about rosuvastatin 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 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 the adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

The safety profile of rosuvastatin is well known and adequately addressed in the product information. Hence, risks are considered not important for the inclusion in the RMP.

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 rosuvastatin.

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

There are no studies required for rosuvastatin.