Part VI: Summary of the risk management plan

Summary of risk management plan for Rosuvastatin 5mg, 10mg, 20mg and 40mg Film-Coated Tablets

This is a summary of the Risk Management Plan (RMP) for Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets. The RMP details important risks of Rosuvastatin, how these risks can be minimised, and how more information will be obtained about Rosuvastatin risks and uncertainties (missing information).

Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablet's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets should be used.

I. The medicine and what it is used for

Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets are indicated for the treatment of the following

Treatment of Hypercholesterolaemia

Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate.

Adults, adolescents and children aged 6 years or older wit homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate.

Prevention of cardiovascular disease

Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

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 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.

II.A List of important risks and missing information

Important risks of Rosuvastatin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

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 Rosuvastatin. 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 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.