

Part VI: Summary of the risk management plan

Summary of risk management plan for Rosuvastatin calcium/Acetylsalicylic acid IBSA 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard

(rosuvastatin calcium/acetylsalicylic acid)

This is a summary of the risk management plan (RMP) for Rosuvastatin calcium/Acetylsalicylic IBSA acid 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard. The RMP details important risks of the product, how these risks can be minimised, and how more information will be obtained about Rosuvastatin calcium/Acetylsalicylic acid capsules, hard's risks and uncertainties (missing information).

Rosuvastatin calcium/Acetylsalicylic IBSA acid 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the product has to be used.

Important new concerns or changes to the current ones will be included in updates of Rosuvastatin calcium/Acetylsalicylic acid 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard's RMP.

I. The medicine and what it is used for

Rosuvastatin calcium/Acetylsalicylic IBSA acid 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard is authorised for substitution therapy for those patients who are adequately controlled with rosuvastatin and acetylsalicylic acid given concurrently, at the same dose level as in the combination. The medicinal product is indicated for secondary prevention: reduction of cardiovascular mortality and morbidity in patients with a history of myocardial infarction or unstable angina pectoris and with either normal or increased cholesterol levels (see SmPC for the full indication). It contains rosuvastatin calcium and acetylsalicylic acid as the active substances and it is given by mouth.

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

Important risks of Rosuvastatin calcium/Acetylsalicylic IBSA acid 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard, together with measures to minimise such risks and the proposed studies for learning more about the product, 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.

If important information that may affect the safe use of Rosuvastatin calcium/Acetylsalicylic acid 5 mg/100 mg, capsules, hard is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rosuvastatin calcium/Acetylsalicylic IBSA acid 5 mg/100 mg, 10 mg/100 mg, 20 mg/100 mg, capsules, hard, capsules, hard 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 the product. 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	Hepatic failure (including hepatic necrosis and fulminant hepatitis)
Missing information	None

II.B Summary of important risks

The safety information in the proposed 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 the product.

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

There are no other studies required for the product in post-authorisation development.