Part VI: Summary of the risk management plan

Summary of risk management plan for Rosuvastatin Alkaloid-INT (Rosuvastatin)

This is a summary of the risk management plan (RMP) for Rosuvastatin Alkaloid-INT. The RMP details important risks of Rosuvastatin Alkaloid-INT, how these risks can be minimised, and how more information will be obtained about Rosuvastatin Alkaloid-INT's risks and uncertainties (missing information).
Rosuvastatin Alkaloid-INT's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rosuvastatin Alkaloid-INTshould be used.
Important new concerns or changes to the current ones will be included in updates of Rosuvastatin Alkaloid-INT's RMP.

I. The medicine and what it is used for

Rosuvastatin Alkaloid-INTis authorised for treatment of hypercholesterolaemia and prevention of cardiovascular events (see SmPC for the full indication). It contains rosuvastatin as the active substance and it is given by oral administration as 5-10-20-40 mg film-coated tablets.

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

Important risks of Rosuvastatin Alkaloid-INT, together with measures to minimise such risks and the proposed studies for learning more about Rosuvastatin Alkaloid-INT's 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, 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 Alkaloid-INT is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rosuvastatin Alkaloid-INT 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 Rosuvastatin Alkaloid-INT. 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 *(from Part II: Module SVIII)*

Important identified risks	- Rhabdomyolysis - Myopathy, myositis, myalgia, CK increases, myoglobinuria and myoglobinaemia (in the setting of rhabdomyolysis and myopathy) - Increased transaminases, hepatitis, jaundice - Pancreatitis - Proteinuria - Diabetes mellitus - Immune-mediated necrotising myopathy - Thrombocytopenia/decreased platelet count - Stevens-Johnson syndrome/toxic epidermal necrolysis - Tendon disorders - Peripheral neuropathy - Drug interactions: ciclosporin, various protease inhibitor combinations with ritonavir, clopidogrel, gemfibrozil, eltrombopag, dronedarone, warfarin, other vitamin K antagonists, ezetimibe,fusidic acid and simeprevir.
Important potential risks	- Renal failure (including acute and chronic renal failure) and renal impairment - Hepatic failure: including hepatic necrosis and fulminant hepatitis - Amyotrophic Lateral Sclerosis - Interstitial lung disease - Drug-drug interaction with fibrates (other than gemfibrozil)
Missing information	- Children under 6 years of age - DDI studies in the paediatric population

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product and comments from RMS's and CMS's assessors are incorporated within.

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 Alkaloid-INT.

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

There are no studies required for Rosuvastatin Alkaloid-INT.