Summary of the risk management plan for Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets.

Names of the product in the RMS are the following: Rosuvastatin Medical Valley 5mg & 10mg & 20mg & 40mg filmovertrukne tabletter; Rosuvastatin "Liconsa" 5mg & 10mg & 20mg & 40mg film coated tablets; Rosuvastatin "Universal Farma" 5mg & 10mg & 20mg & 40mg film coated tablets; Rosval 5mg & 10mg & 20mg & 40mg film coated tablets.

This is a summary of the risk management plan (RMP) for Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets. The RMP details important risks of Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets, how these risks can be minimised, and how more information will be obtained about Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets risks and uncertainties (missing information).

Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets should be used.

I. The medicine and what it is used for

Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets is authorised for the 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 route.

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

Important risks of Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets 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.

If important information that may affect the safe use of Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets 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 5mg & 10mg & 20mg & 40mg film coated tablets. 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).

Table 2. Summary of Safety Concerns

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 5mg & 10mg & 20mg & 40mg film coated tablets.

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

There are no studies required for Rosuvastatin 5mg & 10mg & 20mg & 40mg film coated tablets.