Part VI: Summary of the risk management plan

Summary of risk management plan for Atorvastatin 1A Farma (Atorvastatin)

This is a summary of the risk management plan (RMP) for Atorvastatin 1A Farma. The RMP details important risks of Atorvastatin 1A Farma and how more information will be obtained about Atorvastatin 1A Farma's risks and uncertainties (missing information).

Atorvastatin 1A Farma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atorvastatin 1A Farma should be used.

Important new concerns or changes to the current ones will be included in updates of Atorvastatin 1A Farma's RMP.

I. The medicine and what it is used for

Atorvastatin 1A Farma is authorised to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed and to reduce such risk even if the cholesterol levels are normal, when there is an increased risk of heart disease. (See SmPC for the full indication).

It contains Atorvastatin 1A 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 Atorvastatin 1A Farma, 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*.

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*.

II.A. List of important risks and missing information

Important risks of Atorvastatin 1A Farma 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 Atorvastatin 1A Farma.

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	• Skeletal muscle effects (including Immune-mediated necrotizing myopathy), rhabdomyolysis and rhabdomyolysis-related events • Hepatic failure
Important potential risks	• Haemorrhagic stroke in patients with prior haemorrhagic stroke or lacunar infarct
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 Atorvastatin 1A Farma.

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

There are no studies required for Atorvastatin 1A Farma.