Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for ATORVASTATIN 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets

This is a summary of the risk management plan (RMP) for ATORVASTATIN 10 mg, 20 mg, 40 mg, and 80 mg film-coated tablets, (hereinafter referred to as Atorvastatin). The RMP details important risks of Atorvastatin, how these risks can be minimised, and how more information will be obtained about Atorvastatin's risks and uncertainties (missing information).

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

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

I. The Medicine and What It is used for

Atorvastatin is authorised for hypercholesterolaemia and prevention of cardiovascular diseases (see SmPC for the full indication). It contains atorvastatin as the active substance and it is given orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Atorvastatin, together with measures to minimise such risks and the proposed studies for learning more about Atorvastatin'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, 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 atorvastatin is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of Atorvastatin 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. 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 4: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• Hepatic failure • Skeletal muscle effects, rhabdomyolysis and rhabdomyolysis-related events • Hyperglycaemia, which may require diabetes care in patients with diabetes risk factors • Stevens-Johnson syndrome and toxic epidermal necrolysis • Interstitial lung disease • Concomitant use of coumarin anticoagulants/ warfarin
Important potential risks	• Haemorrhagic stroke • Autoimmune events
Missing information	• Use in paediatric patients < 10 years of age

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.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Atorvastatin.