Part VI: Summary of the risk management plan

Summary of risk management plan for Atorvastatin Aristo 10 mg / 20 mg / 30 mg / 40 mg / 60 mg / 80 mg film-coated tablets (atorvastatin)

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

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

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

I. The medicine and what it is used for

Atorvastatin Aristo is authorised for:

- Hypercholesterolaemia:

  Atorvastatin Aristo is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

  Atorvastatin Aristo is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

- Prevention of cardiovascular disease:

  Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

It contains atorvastatin 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 Aristo, together with measures to minimise such risks and the proposed studies for learning more about Atorvastatin Aristo'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 Periodic Safety Update Report (PSUR) assessment, 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 Aristo 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 Aristo. 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	Toxic liver injury. Rhabdomyolysis (including cases due to increased plasma levels of atorvastatin in concomitant use of CYP3A4 inhibitor). Bleeding due to concomitant use of coumarin anti-coagulant agents.
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 Atorvastatin Aristo.

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

There are no studies required for Atorvastatin Aristo.