Part VI: Summary of the risk management plan

Summary of risk management plan for Atorvastatin.

This is a summary of the risk management plan (RMP) for 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). The RMP is in line with the final agreed SPC.

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.

I. The medicine and what it is used for

Hypercholesterolaemia

Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDLC), 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 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 calcium 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 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 leaflets and SmPCs 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 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 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).

The below safety concerns were considered from CMDh website of Atorvastatin Zentiva (version 1.0, dated 1 July 2019, CZ/H/0868/001-006/DC).

Important Identified Risk	• Hepatic failure • Skeletal muscle effects, rhabdomyolysis and rhabdomyolysis-related events • Concomitant use of coumarin anticoagulants / warfarin
Important Potential Risk	• 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

No post authorisation study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or which are a specific obligation of Atorvastatin.

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

There are no studies required for Atorvastatin.