13 Part VI: Summary of the risk management plan for Atorvastatin calcium*, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg; Film-coated tablets

* in Reference member state (RMS)-Austria (AT)
Atorvastatin Sandoz 10 mg - Filmtabletten,
Atorvastatin Sandoz 20 mg - Filmtabletten,
Atorvastatin Sandoz 30 mg - Filmtabletten,
Atorvastatin Sandoz 40 mg - Filmtabletten,
Atorvastatin Sandoz 60 mg - Filmtabletten,
Atorvastatin Sandoz 80 mg - Filmtabletten

This is a summary of the risk management plan (RMP) for atorvastatin calcium*, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg, film-coated tablets. The RMP details important risks of atorvastatin calcium*, film-coated tablets, how these risks can be minimized, and how more information will be obtained about atorvastatin calcium*, film-coated tablets' risks and uncertainties (missing information).

Atorvastatin calcium*, film-coated tablet's summaries of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how atorvastatin calcium*, film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the atorvastatin calcium*, film-coated tablets' RMP.

13.1 Part VI: I. The medicine and what it is used for

Atorvastatin calcium*, is authorized for:

Hypercholesterolemia

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

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

Prevention of cardiovascular disease (CVD)

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 an active substance and is taken orally as film-coated tablets (10 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of atorvastatin calcium*, film-coated tablets, together with measures to minimize such risks and the proposed studies for learning more about atorvastatin calcium*, film-coated tablets' risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PLs and SmPCs addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of atorvastatin calcium*, film-coated tablets are risks that need special risk management activities to further investigate or minimize 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 calcium*, 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 13-1 List of important risks and missing information

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	Hemorrhagic stroke in patients with prior hemorrhagic stroke or lacunar infarct
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies, which are conditions of the marketing authorization or specific obligation for atorvastatin calcium*, film-coated tablets.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for atorvastatin calcium*, film-coated tablets.