Part VI: Summary of the risk management plan

Summary of risk management plan for ezetimibe/atorvastatin

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

Ezetimibe/atorvastatin's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ezetimibe/atorvastatin should be used. Important new concerns or changes to the current ones will be included in updates of ezetimibe/atorvastatin's RMP.

I. The medicinal product and what it is authorised for

Ezetimibe/atorvastatin as an adjunct to diet is indicated as substitution therapy for treatment of adults with primary (heterozygous and homozygous familial and non-familial) hypercholesterolaemia or mixed hyperlipidaemia already controlled with atorvastatin and ezetimibe given concurrently at the same dose level.

It contains ezetimibe and atorvastatin as the active substances and it is administered orally. The strengths of the tablets available are

- ezetimibe 10 mg/atorvastatin 10 mg film-coated tablets

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of ezetimibe/atorvastatin, together with measures to minimise such risks and the proposed studies for learning more about ezetimibe/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.

If important information that may affect the safe use of ezetimibe/atorvastatin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of ezetimibe/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 ezetimibe/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)

Summary of safety concerns	
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	• Use in children less than 18 years of age • Use in patients with moderate or severe liver problems

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 ezetimibe/atorvastatin.

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

There are no studies required for ezetimibe/atorvastatin.