Part VI: Summary of the risk management plan

Summary of risk management plan for Ezetimibe/Simvastatin Accord Tablets (ezetimibe and simvastatin)

This is a summary of the risk management plan (RMP) for Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets. The RMP details important risks of Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets, how these risks can be minimised, and how more information will be obtained about Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablet's risks and uncertainties (missing information).

Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ezetimibe/Simvastatin Accord10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablet's RMP.

I. The medicine and what it is used for

Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablet is indicated for following indications.

Prevention of Cardiovascular Events

Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg tablet is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.

Hypercholesterolaemia

Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg tablet is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia or mixed hyperlipidaemia where use of a combination product is appropriate:

- Patients not appropriately controlled with a statin alone
- Patients already treated with a statin and ezetimibe

Homozygous Familial Hypercholesterolaemia (HoFH)

Ezetimibe/Simvastatin Accord tablet is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g., low-density lipoprotein [LDL] apheresis).

It contains ezetimibe and simvastatin as the active substances and it is given orally.

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

Important risks of Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets, together with measures to minimise such risks and the proposed studies for learning more about Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablet'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 signal management activity, 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 Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets 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/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg 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).

Important identified risks	• Rhabdomyolysis / Myopathy • Abnormal liver function
Important potential risks	• New onset diabetes mellitus / impaired glucose metabolism
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 authorization or specific obligation of Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets.

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

There are no studies required for Ezetimibe/Simvastatin Accord 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg Tablets as post-authorisation development plan.