Summary of risk management plan for ezetimibe by Krka

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

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

Important new concerns or changes to the current ones will be included in updates of ezetimibe by Krka's RMP.

I. The medicine and what it is used for

Ezetimibe by Krka is authorised:

- For primary hypercholesterolaemia and homozygous familial hypercholesterolaemia (HoFH) co-administred with HMG-CoA reductase inhibitor (statin)
- For prevention of cardiovascular events
- As adjunctive therapy diet for use in patients with homozygous familial sitosterolaemia

(see SmPC for the full indication)

It contains ezetimibe 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 ezetimibe by Krka, together with measures to minimise such risks and the proposed studies for learning more about ezetimibe by Krka'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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

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

II.A List of important risks and missing information

Important risks of ezetimibe by Krka 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 by Krka. 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	Rhabdomyolysis / Myopathy Abnormal liver function Hypersensitivity Drug interaction with warfarin, another coumarin anticoagulant or fluindione Drug interaction with ciclosporin
Important potential risks	Cholecystitis/Cholelithiasis Pancreatitis
Missing information	Exposure during pregnancy and lactation Limited clinical trial experience in children age 10 to 17 years old beyond 1 year and in children 6 to 10 years old beyond 12 weeks. No clinical trial experience in children less than 6 years of age.

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 by Krka.

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

There are no studies required for ezetimibe by Krka.