Part VI: Summary of the risk management plan

Summary of risk management plan for Tritilz 10mgTablets

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

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

I. The medicine and what it is used for

Tritilz is authorised for primary hypercholesterolaemia, the prevention of cardiovascular events, homozygous familial hypercholesterolaemia and homozygous sitosterolaemia (see SmPC for the full indication). It contains ezetimibe as the active substance and it is given by oral route of administration.

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

Important risks of Tritilz, together with measures to minimise such risks and the proposed studies for learning more about Tritilz'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 Tritilz is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tritilz 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 Tritilz. 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 • Limited exposure in children aged 10 to 17 beyond 1 year • Limited exposure in children less than 10 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

Not applicable