

Part VI: Summary of the risk management plan

Summary of risk management plan for Intestat 10 mg tablet (ezetimibe)

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

Intestat 10 mg tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Intestat 10 mg tablet should be used.

I. The medicine and what it is used for

Intestat 10 mg tablet is authorised for primary hypercholesterolaemia, prevention of cardiovascular events, homozygous familial hypercholesterolaemia (HoFH) and homozygous familial sitosterolaemia (see SmPC for the full indication). It contains ezetimibe as the active substance and it is given by oral tablet, containing 10 mg ezetimibe.

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

Important risks of Intestat 10 mg tablet, together with measures to minimise such risks and the proposed studies for learning more about Intestat 10 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 PSUR assessment -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 Intestat 10 mg tablet is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Intestat 10 mg tablet are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered / 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 Intestat 10 mg tablet. 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	#1. Rhabdomyolysis/Myopathy
	#2. Abnormal liver function
	#3. Hypersensitivity
	#4. Drug interaction with warfarin, another coumarin anticoagulant or fluindione
	#5. Drug interaction with ciclosporin
Important potential risks	#6. Cholecystitis/Cholelithiasis
	#7. Pancreatitis
Missing information	#8. Exposure during pregnancy and lactation
	#9. 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 Intestat.

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

There are no studies required for Intestat 10 mg tablet.