Part VI: Summary of the risk management plan

Summary of risk management plan for Ketosteril film coated tablets

This is a summary of the risk management plan (RMP) for Ketosteril film-coated tablets. The RMP details important risks of Ketosteril film-coated tablets, how these risks can be minimised, and how more information will be obtained about Ketosteril film-coated tablets's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Ketosteril film-coated tablets's RMP.

I. The medicine and what it is used for

Ketosteril film-coated tablets is authorised for prevention and treatment of damages due to faulty or deficient protein metabolism in chronic kidney disease in connection with a limited dietary protein intake of 40 g/day or less (adult) (see SmPC for the full indication). It contains RS)-3-methyl-2-oxovaleric acid (α-ketoanalogue to DL-isoleucine), calcium-salt, 2-oxo-3-phenylpropionic acid (α-ketoanalogue to phenylalanine), calcium-salt, 3-methyl-2-oxobutyric acid (α-ketoanalogue to valine), calcium salt, (RS)-2-hydroxy-4-methylthio-butyric acid (α-hydroxyanalogue to DL-methionine), calcium-salt, L-lysine acetate, corresponding to 75 mg L-lysine, L-threonine, L-tryptophan, L-histidine,L-tyrosine as active substances and it is given by oral route.

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

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

II.A List of important risks and missing information

Important risks of Ketosteril film-coated 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 Ketosteril film-coated 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks or missing information

Not applicable as there is no important identified risk, important potential risk and missing information.

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 Ketosteril film-coated tablets.

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

There are no studies required for Ketosteril film-coated tablets.