Part VI: Summary of the risk management plan

Summary of risk management plan for eplerenone by Krka

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

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

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

I. The medicine and what it is used for

Eplerenone by Krka is indicated in addition to standard therapy including beta-blockers, to reduce the risk of cardiovascular (CV) mortality and morbidity in stable patients with left ventricular dysfunction (LVEF ≤ 40 %) and clinical evidence of heart failure after recent myocardial infarction (MI) and in addition to standard optimal therapy, to reduce the risk of CV mortality and morbidity in adult patients with New York Heart Association (NYHA) class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%) (see SmPC for the full indication). It contains eplerenone 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 eplerenone by Krka, together with measures to minimise such risks and the proposed studies for learning more about eplerenone 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 eplerenone 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 eplerenone 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 eplerenone 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	Hyperkalaemia Renal impairment
Important potential risks	None
Missing information	Use during pregnancy and lactation Use in children and adolescents

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 eplerenone by Krka.

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

There are no studies required for eplerenone by Krka.