Summary of risk management plan for Eplerenone 25 mg and 50 mg Film-Coated Tablets for solution for infusion

This is a summary of the risk management plan (RMP) for Eplerenone 25 mg and 50 mg FilmCoated Tablets. The RMP details important risks of Eplerenone, how these risks can be minimised, and how more information will be obtained about Eplerenone risks and uncertainties (missing information).

Eplerenone 25 mg and 50 mg Film-Coated Tablet's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Eplerenone 25 mg and 50 mg Film-Coated Tablets should be used.

I. The medicine and what it is used for

Eplerenone 25 mg and 50 mg Film-Coated Tablets is indicated:

- in addition to standard therapy including beta-blockers, to reduce the risk of cardiovascular mortality and morbidity in stable patients with left ventricular dysfunction (LVEF ≤ 40 %) and clinical evidence of heart failure after recent myocardial infarction.

- in addition to standard optimal therapy, to reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤30%).

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

Important risks of Eplerenone, together with measures to minimise such 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; x 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 Eplerenone 25 mg and 50 mg Film-Coated Tablet is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Eplerenone are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

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. 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	x Hyperkalemia x Renal Impairment
Important potential risks	x None
Missing information	x Use in patients who are pregnant or breast-feeding x 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.

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

There are no studies required for Eplerenone.