Summary of risk management plan for Eplerenone Bluefish (eplerenone)

This is a summary of the risk management plan (RMP) for Eplerenone Bluefish. The RMP details important risks of Eplerenone Bluefish, which can be minimized through routine risk minimisation measures and more information will be obtained about Eplerenone Bluefish's risks and uncertainties (missing information) through routine pharmacovigilance activities.

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

Important new concerns or changes to the current ones will be included in updates of Eplerenone Bluefish's RMP.

I. The medicine and what it is used for

Eplerenone Bluefish is authorised for:

- 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)
- 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 section 5.1 of SmPC).

It contains eplerenone as the active substance, and it is given orally as 25 mg and 50 mg film-coated tablets.

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

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

II.A List of important risks and missing information

Important risks of Eplerenone Bluefish 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 Bluefish. 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 in patients who are pregnant or breast feeding • 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 Bluefish.

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

There are no studies required for Eplerenone Bluefish.