Part VI: Summary of the risk management plan for Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets

This is a summary of the risk management plan (RMP) for Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets. The RMP details important risks of Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets how these risks can be minimised, and uncertainties (missing information).

Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the drugs should be used.

I. The medicine and what it is used for

Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets is indicated for the treatment of:

- To treat high blood pressure (hypertension),
- To reduce the risk of you having a heart attack or stroke,
- To reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes),
- To treat your heart when it cannot pump enough blood to the rest of your body (heart failure),
- As treatment following heart attack (myocardial infarction) complicated with heart failure.

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

Important risks of Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets, together with measures to minimise such risks, are outlined below.

Measures to minimise the risks identified are:

- 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 medicine's legal status- Prescription only product.

Together, these measures constitute routine risk minimisation measures.

No additional risk minimisation measures are proposed.

In addition to these measures, routine pharmacovigilance activities including adverse reactions reporting, PSUR, medical literature monitoring, and other activities as required under EU legislation, are made.

No additional risk minimisation measures are proposed.

If important information that may affect the safe use Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets is not yet available, it is listed under missing information (Exposure during breast feeding).

II. A. List of important risks and missing information

Important risks of Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg tablets 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 Ramipril Antibiotice 2,5 mg, 5 mg, 10 mg 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.

Summary of safety concerns	
Important identified risks	1. Hyperkalaemia 2. (Symptomatic) hypotension 3. Hypersensitivity reactions incl. angioedema 4. Foetotoxicity 5. Renal failure
Important potential risks	Not identified
Missing information	1. Exposure during breast feeding

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

Not applicable

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

Not applicable