Part VI: Summary of the risk management plan

Summary of risk management plan for Alkacit 10 mEq modified-release tablets (Potassium citrate)

This is a summary of the risk management plan (RMP) for Alkacit 10 mEq modified-release tablets. The RMP details important risks of Alkacit 10 mEq modified-release tablets, how these risks can be minimised and how more information will be obtained about Alkacit 10 mEq modified-release tablets's risks and uncertainties (missing information).

Alkacit 10 mEq modified-release tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Alkacit 10 mEq modified-release tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Alkacit 10 mEq modified-release tablets 's RMP.

I. The medicine and what it is used for

Alkacit 10 mEq modified-release tablets is an alkalizing agent and indicated in adults for:

- The treatment of patients with kidney stones and hypocitraturia, or chronic calcium oxalate stones.
- The treatment and prevention of recurrent uric acid lithiasis with or without calcium lithiasis and cystine lithiasis.

The treatment of renal tubular acidosis with calcium nephrolithiasis (see SmPC for the full indication).

It contains potassium citrate as the active substance, and it is given by oral use.

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

Important risks of Alkacit 10 mEq modified-release tablets, together with measures to minimise such risks and the proposed studies for learning more about Alkacit 10 mEq modified-release 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.

II.A List of important risks and missing information

Important risks of Alkacit 10 mEq modified-release 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 Alkacit 10 mEq modified-release 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

Risks associated with Alkacit 10 mEq modified-release tablets use are considered well-characterized and sufficiently managed by routine risks minimisation measures.

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 Alkacit 10 mEq modified-release tablets.

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

There are no studies required for Alkacit 10 mEq modified-release tablets.