Summary of the risk management plan

Summary of risk management plan for RENOCIS 1 mg kit for radiopharmaceutical preparation (dimercaptosuccinic acid, DMSA)

This is a summary of the risk management plan (RMP) for RENOCIS 1 mg kit for radiopharmaceutical preparation. The RMP details important risks of RENOCIS 1 mg kit for radiopharmaceutical preparation. how these risks can be minimised, and how more information will be obtained about RENOCIS 1 mg kit for radiopharmaceutical preparation risks and uncertainties (missing information).

RENOCIS 1 mg kit for radiopharmaceutical preparation summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how RENOCIS 1 mg kit for radiopharmaceutical preparation should be used.

Important new concerns or changes to the current ones will be included in updates of RENOCIS 1 mg kit for radiopharmaceutical preparation RMP.

I. The medicine and what it is used for

RENOCIS 1 mg kit for radiopharmaceutical preparation is authorised for static (planar or tomographic) renal imaging: morphological studies of renal cortex; individual kidney function; location of ectopic kidney. It contains dimercaptosuccinic acid as the active substance and it is given by intravenous route of administration

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

Important risks of RENOCIS 1 mg kit for radiopharmaceutical preparation, together with measures to minimise such risks and the proposed studies for learning more about RENOCIS 1 mg kit for radiopharmaceutical preparation risks, are outlined below.

Measures to minimise the risks identified for medicinal products include specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR 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 RENOCIS 1 mg kit for radiopharmaceutical preparation is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of RENOCIS 1 mg kit for radiopharmaceutical preparation 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 RENOCIS 1 mg kit for radiopharmaceutical preparation. 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

Not Applicable

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 RENOCIS 1 mg kit for radiopharmaceutical preparation.

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

There are no studies required for RENOCIS 1 mg kit for radiopharmaceutical preparation.