Part VI: Summary of activities in the risk management plan

Summary of risk management plan for Renoscint (MAG3) Kit for radiopharmaceutical preparation

This is a summary of the risk management plan (RMP) for Renoscint (MAG3) Kit for radiopharmaceutical preparation. The RMP details important risks, how these risks can be minimised, and how more information will be obtained about Renoscint (MAG3) Kit for radiopharmaceutical preparation risks and uncertainties (missing information).
Renoscint (MAG3) Kit for radiopharmaceutical preparation summary of product characteristics (SmPC) and patient leaflet give essential information to healthcare professionals and patients on how the product should be used.

I. The medicine and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.
Renoscan MAG3 is used through a scan to examine the:

- kidneys
- urine output and
- bladder

This medicine is a powder. When mixed by qualified people, with a solution of a radioactive substance, sodium pertechnetate (99mTc) it forms Technetium (99mTc) tiatide. When injected into the body it collects in certain organs such as kidneys.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioacticity within the organ and body. This also gives the doctor valuable information about the structure and function of the organ.

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

Important risks of Renoscint MAG3 Kit for radiopharmaceutical preparation, together with measures to minimise such risks and the proposed studies for learning more about Renoscint MAG3 Kit for radiopharmaceutical preparation'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 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 conctitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Renoscint (MAG3) 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 Renoscint (MAG3) 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 and missing information

The safety information in the proposed Product Information is aligned to the reference 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 Renoscint (MAG3) Kit for radiopharmaceutical preparation.

II.C.2 Other studies in 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 Renoscint MAG3 Kit for radiopharmaceutical preparation.

II.C.2 Other Studies in Post-Authorisation Development Plan
There are no studies which are conditions of the marketing authorisation or specific obligation of Renoscint MAG3 Kit for radiopharmaceutical preparation.