Part VI: 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.

The main safety concerns for RENOCIS 1 mg kit for radiopharmaceutical preparation are carcinogenicity and hereditary effect, Occupational and inadvertent exposure to radiation, risk of misdiagnosis- drug ineffectiveness and safety in pregnant or breastfeeding women.

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

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 assessment, 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	Carcinogenicity and hereditary effects Occupational and inadvertent exposure to radiation Risk of misdiagnosis-drug ineffectiveness Safety in pregnant or breastfeeding women
Missing information	None

II.B Summary of important risks

Important potential risk: Carcinogenicity and hereditary effects	
Evidence for linking the risk to the medicine	Carcinogenicity and hereditary effects is considered as Important Potential Risk as ionizing radiation is linked with cancer induction and can lead to development of hereditary defects via radiation induces DNA-damage. This evaluation is based on the known effect of radiation on tissues (extrapolation of epidemiological data observed in dose ranges of medium and high radiation doses), available published literature, and product's SmPC.
Risk factors and risk groups	All patients and particularly young patients and children.
Risk minimisation measures	Routine risk minimisation measures For each patient, the radiation exposure must be justifiable by the likely benefit. The amount administered should be as low as possible to obtain the required scans. This medicinal product is for use in hospitals or in designated nuclear medicine facilities only. Additional risk minimisation measures None.

Important potential risk: Occupational and inadvertent exposure to radiation	
Evidence for linking the risk to the medicine	Occupational and inadvertent exposure to radiation is considered as Important Potential Risk as ionizing radiation is linked with cancer induction and can lead to development of hereditary defects via radiation induces DNA-damage. This evaluation is based on the known effect of radiation on tissues (extrapolation of epidemiological data observed in

	dose ranges of medium and high radiation doses), available published literature, and product's SmPC.
Risk factors and risk groups	NA
Risk minimisation measures	Routine risk minimisation measures This medicinal product is for use in hospitals or in designated nuclear medicine facilities only. Additional risk minimisation measures None.

Important potential risk: Risk of misdiagnosis - drug ineffectiveness	
Evidence for linking the risk to the medicine	Risk of misdiagnosis - drug ineffectiveness is considered as Important Potential Risk as it may result in delayed diagnosis, unnecessary and/or repeat examinations. This evaluation is based on available published literature, safety database data, Product Quality Claim register and product's SmPC.
Risk factors and risk groups	All patients and particularly patients treated with medicaments which may affect the function of tested organs and influence the uptake of technetium (^{99m}Tc) succimer ([^{99m}Tc] DMSA).
Risk minimisation measures	Routine risk minimisation measures Advice is given on potential drug-drug interactions, which may influence the uptake of technetium (^{99m}Tc) succimer ([^{99m}Tc] DMSA). To avoid these influences, patient's medications have to be assessed and interrupted where possible before administration of technetium (^{99m}Tc) succimer ([^{99m}Tc] DMSA). This medicinal product is for use in hospitals or in designated nuclear medicine facilities only. Additional risk minimisation measures None.

Important potential risk: Safety in pregnant or breastfeeding women	
Evidence for linking the risk to the medicine	Safety in pregnant or breastfeeding women is considered as Important Potential Risk as radionuclide procedures carried out on pregnant women involve radiation doses to the foetus. This evaluation is based on available published literature and product's SmPC.
Risk factors and risk groups	Pregnant and breastfeeding women

Risk minimisation measures	Routine risk minimisation measures Advice given on determination of pregnancy before administration of technetium (^{99m}Tc) succimer ([^{99m}Tc] DMSA). Instruction to offer alternative techniques not using of technetium (^{99m}Tc) succimer ([^{99m}Tc] DMSA) if a woman is pregnant or there is doubt about a potential pregnancy. If the administration is considered necessary in breastfeeding woman, breastfeeding should be interrupted for 12 hours and the expressed feeds discarded. This medicinal product is for use in hospitals or in designated nuclear medicine facilities only. Additional risk minimisation measures None.

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.