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Elements for a Public Summary

Risk management plan (RMP) in the EU for Generics

(based on the version 10 April 2013; EMA/717051/2012; Patient Health Protection)

Active substance(s) (INN or common name):	Technetium (99mTc) tiatide
Pharmaco-therapeutic group (ATC Code):	V 09 CA 03
Name of Marketing Authorisation Holder or Applicant:	Medi-Radiopharma Ltd., Szamos street 10-12. HU-2030 Érd Hungary
Number of medicinal products to which this RMP refers:	1
Product(s) concerned (brand name(s)):	Renoscint (MAG3) Kit for radiopharmaceutical preparation

Data lock point for this RMP	15th Aug 2016	Version number	1.1
Date of final sign off	4thApr 2017		

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Renal artery blockage (stenosis) is a common disorder which can cause kidney function loss and/or treatment-resistant high blood pressure (hypertension).

European and US populations are ageing ones, further raising the possibility of increasing renal artery stenosis. The occurrence of renal artery stenosis in a single kidney in elderly people is found to be very high (75%) and can ultimately result in renal failure.

Chronic and acute renal failure are very common disorders. Chronic renal failure is typically caused by chronic hypertension or diabetes mellitus. The most common causes of acute renal failure are the acute disorders of renal perfusion and post-renal obstruction of the urinary tract.

VI.2.2 Summary of treatment benefits

The use of technetium-99m mercaptoacetyltriglycine (MAG3) has been having increasing significance since its introduction in 1986. 99mTc MAG3 has become the radiopharmaceutical

of choice in many clinical contexts, particularly for patients with suspected obstruction or impaired renal function.

After reconstitution and labelling with sodium (99mTc) pertechnetate solution, the diagnostic agent technetium (99mTc) tiatide may be used for the evaluation of nephrological and urological disorders in particular for the study of morphology, perfusion, and function of the kidney and characterisation of urinary outflow.

The technique is very useful in evaluating the functioning of kidneys. Radioisotope can differentiate between passive dilatation and obstruction. It is widely used in differentialdiagnosis of treatment-resistant hypertension and before renal transplantation to assess the vascularity of the kidney to be transplanted and with a test dose of captopril to highlight possible renal artery stenosis in the donor's other kidney, and later the performance of the transplant.

VI.2.3 Unknowns relating to treatment benefit

To date no information is available about the application of Renoscint (MAG3) in case of pregnant and lactating women.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
None	NA	NA

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Pregnant and lactating women	The chance that someone is given a radioactive diagnostic kit when pregnant or lactating is very low as the patient is asked about it before being injected. If the diagnostic agent absolutely must be administered information should be collected.
Occupational and inadvertent exposure to ionizing radiation	Exposure to ionisation radiation is linked with cancer induction and a potential for development of hereditary defects. For most diagnostic investigations using a nuclear medicine procedure, the effective dose is less than 20 mSv, so these adverse effects will occur with low probability. The effective dose of 20mSv is equivalent to the natural annual exposure to ionization radiation. The nuclear medicine department will use the lowest effective radiation dose necessary to perform the diagnosis
Carcinogenicity and hereditary effects	Exposure to ionisation radiation is linked with cancer induction and a potential for development of hereditary defects. For most diagnostic investigations using a nuclear medicine procedure, the effective dose is less than 20 mSv, so these adverse effects will occur with low probability. The effective dose of 20mSv is equivalent to the natural annual exposure to ionization radiation. The nuclear medicine department will use the lowest effective radiation dose necessary to perform the diagnosis

Important missing information

Risk	What is known
Use in paediatric population	Clinical experience indicates that for paediatric use the activity should be reduced. Because of the variable relationship between the size and body weight of patients it is sometimes more satisfactory to adjust activities to body surface area. A practical approach is to adopt the recommendations of the Paediatric Task Group of the European Association of Nuclear Medicine (EANM).

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimization measures. The SmPc PL for Renoscint can be found in Renoscint's EPAR page.
This medicine has no additional risk minimization measures.

VI.2.6 Planned post authorisation development plan

The MAH does not plan post authorization studies in the near future.

List of studies in post authorisation development plan

Study/activity (including study number)	**Objectives**	**Safety concerns /efficacy issue addressed**	**Status**	**Planned date for submission of (interim and) final results**
NA	NA	NA	NA	NA

VI.2.7 Summary of changes to the Risk Management Plan over time

First version

Version	**Date**	**Safety Concerns**	**Comment**
NA	NA	NA	NA