VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

NephroMAG is a radiopharmaceutical product for diagnostic use only. It is used for renal scintigraphy, also known as "renal scanning" or "renal imaging", e.g. for examinations using radioisotopes that evaluate the function and anatomy of the kidneys and urological pathways.

Different types of renal scans are used to examine different aspects of the kidneys and kidney functioning; however, all of these procedures involve the injection of ^{99m}Tc- Mertiatide, an imaging substance that emits a tiny amount of radioactivity, into the patient.

After injection, the radiotracer eventually accumulates in the kidneys, where it gives off energy in the form of gamma rays. This energy is detected by a device called a gamma camera. The camera works with a computer to measure the amount of radiotracer absorbed by the body and to produce special pictures offering details on both the structure and function of organs and tissues.

Common uses are the measurement of renal perfusion and taking function imaging that examines blood flow to the kidneys. Through a series of images taken over 45 minutes immediately after radiotracer injection, it also helps determine how well the kidneys are functioning.

VI.2.2 Summary of treatment benefits

The information provided by renal imaging is unique and often unattainable using other imaging procedures. Renal imaging yields useful information needed to make a diagnosis or to determine appropriate treatment of the underlying disease. Because the doses of radiotracer administered are small, diagnostic nuclear medicine procedures result in relatively low radiation exposure to the patient, acceptable for diagnostic exams. Thus, the radiation risk from the treatment is very low and always outweighed by the potential benefits.

VI.2.3 Unknowns relating to treatment benefits

In the supporting studies for the main indications nearly all patients were white Caucasians. However from the mechanism of transport and accumulation of the radiopharmaceutical there is no reason to presume that diagnostic performance would be any different in none-white patients.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Carcinogenicity and hereditary defects	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 not higher than the exposure to ionization radiation during a computer tomographic examination and is equivalent to the natural annual exposure to ionization radiation.	For each patient, exposure to ionising radiation is justified on the basis of the expected diagnostic benefit in relation to the risk from radiation exposure. The activity administered is as low as necessary to achieve the diagnostic result. The product is always used in compliance with the law regarding protective measures for the use of radioactive pharmaceuticals. Radiopharmaceuticals may be used only by qualified personnel with the appropriate government authorization for the use and manipulation of radionuclides. This radiopharmaceutical may be received, used and administered only by authorized persons in designated clinical settings.
Hypersensitivitiy reaction	Like all medicines, ^{99m}Tc- Mertiatide can cause side effects, although not everybody gets them. In rare cases the application can cause hypersensitivity reactions.	If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product is stopped immediately and intravenous treatment will be initiated, if necessary. To enable immediate action in emergencies, the necessary equipment (such as endotracheal tube and ventilator) is available at a nuclear medicine institution.

Missing information

There is no missing information.

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 minimising 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 minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

A post authorisation development plan will not be carried out.

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

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
01	31.05.2015	● Carcinogenicity and hereditary defects ● Hypersensitivity reactions	Initial Version