Part VI: Summary of activities in the risk management plan

Summary of risk management plan for Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation (technetium (^{99m}Tc)-exametazime)

This is a summary of the risk management plan (RMP) for Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation. The RMP details important risks, how these risks can be minimised, and how more information will be obtained about Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation risks and uncertainties (missing information).
Medi-Exametazim 500 microgram 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.
Medi-Exametazim

I. The medicine and what it is used for

After radiolabelling with sodium pertechnetate (99mTc) solution, the solution of technetium (99mTc) exametazime obtained is indicated for:

Neurology

Technetium (99mTc) exametazime is indicated for use with single photon emission tomography (SPECT).

In brain perfusion SPECT, the diagnostic target is detection of abnormalities of regional cerebral blood flow. The following indications are sufficiently documented:

- Evaluation of patients with cerebrovascular disease (specifically acute stroke, chronic ischemia, and transient ischemic attack)
- Presurgical lateralization and localization of epileptogenic foci.
- Evaluation of patients with suspected dementia (specifically Alzheimer's disease and frontotemporal dementia)

- Evaluation of patients with migraine

Infectious or inflammatory diseases

In infectious or inflammatory diseases, the diagnostic target is tissue or structures in which labeled leukocytes are retained.

In infectious or inflammatory diseases, the following indications are sufficiently documented:

- Localisation of abnormal foci guiding the aetiologic diagnosis in case of fever of unknown origin
- Diagnosis of infection in case of suspected osteomyelitis (with or without implants) and suspected hip or knee prosthesis infection.
- Detection of the extension of inflammation in case of inflammatory bowel disease.

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

Important risks of Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation together with measures to minimise such risks and the proposed studies for learning more about Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation 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 or without 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, including PSUR, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Medi-Exametazim 500 microgram 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 Medi-Exametazim 500 microgram 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

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 Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation.

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

There are no studies required for Medi-Exametazim 500 microgram Kit for radiopharmaceutical preparation.