Part VI: Summary of the risk management

Summary of Risk Management Plan for Medi-MIBI (Copper tetramibi tetrafluoroborate)

This is a summary of the risk management plan (RMP) for Medi-MIBI. The RMP details important risks of Medi-MIBI, how these risks can be minimised, and how more information will be obtained about Medi-MIBI's risks and uncertainties (missing information).

Medi-MIBI's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Medi-MIBI should be used.

Important new concerns or changes to the current ones will be included in updates of Medi-MIBI's RMP.

I. The medicine and what it is used for

Medi-MIBI is for diagnostic use only.

This is indicated for adults.

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

- Myocardial perfusion scintigraphy for the detection and localisation of coronary artery disease (angina pectoris and myocardial infarction)
- Assessment of global ventricular function. First-pass technique for determination of ejection fraction and/or ECG-triggered, gated SPECT for evaluation of left ventricular ejection fraction, volumes and regional wall motion.
- Scintimammography for the detection of suspected breast cancer when mammography is equivocal, inadequate or indeterminate.
- Localisation of hyperfunctioning parathyroid tissue in patients with recurrent or persistent disease in both primary and secondary hyperparathyroidism, and in patients with primary hyperparathyroidism scheduled to undergo initial surgery of the parathyroid glands.

It contains copper tetramibi tetrafluoroborate as active substance and it is given in the form of intravenous injection.

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

Important risks of Medi-MIBI, together with measures to minimise such risks and the proposed studies for learning more about Medi-MIBI'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, including PSUR assessment 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-MIBI are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken.
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-MIBI
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).

Summary of safety concerns	
Important identified risks	Exposure to ionising radiation/occupational exposure
Important potential risks	Risk of misdiagnosis
	In utero exposure
Missing information	none

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal 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-MIBI.

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

There are no studies required for Medi-MIBI.