VI.2 Elements for a Public Summary

Coronary Artery Disease is the most common reason of death. As a consequence chronic stable angina, unstable angina, myocardial infarction, heart failure, death might develop. The determinantion of the stage of the disease or asymptomatic status is pivotal for the therapy of the patient.

Breast cancer is diagnosed in many ways. The primary techniques used for diagnosis are the conventional ones like x-ray and ultra-sound . In the case of the dense, glandular breast types the primary

techniques are not enough. In such cases it is a great help to use imaging techniques in finding the location and the size of dense areas.

Parathyroid disease is a less frequent disease than tumors. It is difficult to find the location of the parathyroid gland. Imaging techniques are essential in setting up the diagnosis.

VI.2.2 Summary of treatment benefits

The location of myocardial ischemia due to coronary artery disease should be mapped by nuclear medicine technique to see the defects in the heart muscle and the cardiac function.

The test can be done both at rest and during exercise (so called stress-test).

After reconciliation of the preparation and injecting it to the patient the imaging of the heart muscles will be possible by the aid of a scintigraphy technique. The assessment of global ventricular function is also possible.

The product can be used for the diagnosis of breast cancer and parathyroid imaging also by injecting a different dose.

The diagnostic kit is prepared at the nuclear medicine departments under the supervision of the qualified personnel. The use of the diagnostic kits in the nuclear medicine departments is followed by the local and international standards and regulations.
Only qualified users at the nuclear medicine departments are allowed to perform these diagnostic tests with isotopes.

Package leaflet is provided with the kit which is written for both the qualified users and patients.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
NA		

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
interactions with concomitant medications	Patient counselling prior to diagnosis is necessary to check whether or not other illnesses are present and/or what medications are being taken. This is to avoid false results during diagnosis.
underdose/overdose	Overdose or underdose is possible if the weight of the patient is not known precisely and so the amount of injected dose is not calculated well; if the injection was not complete; if the circulation in an impaired tissue is slowed down so the dose cumulates somewhere in the body.

Important missing information

Risk	What is known
frequency of hypersensitivity	The hypersensitivity is a pharmacological class effects might have a safety concern with the medicinal product. No clinical data are available to support the frequency of these effects.
toxicity data on patients with • impaired renal or • cardiac function is not known.	Medi-MIBI is eliminated from the body via the kidneys and faeces. To date there are no specific studies performed in patients with kidney or heart problems.

VI.2.5 Summary of risk minimisation measures by safety concern

Medication errors

We categorized the medication errors:

a) Medication errors due to preparation are very rare and controlled locally at the site of preparation. This process is regulated by the Nuclear Medicine Society the and its control is not the responsibility of the MAH though joint activity can be organised. Only qualified personnel working at the nuclear medicine departments –supervised by the Nuclear Safety Officer - can prepare and inject the diagnostic drug.

b) Patient counseling and preparation error may arise if the patient is examined thoroughly, if not questioned nor consented properly. Overdose or underdose is possible if the weight of the patient is not known precisely and so the amount of injected dose is not calculated well; if the injection was not complete; if the circulation in an impaired tissue is slowed down so the dose cumulates somewhere in the body.

c) Post-diagnostic information from the patient might not be obtained after the patient left. The nuclear medicine staff should report any event occurred after the diagnosis has finished or even days after if the patient reports any event to them.

Medication Error	Likelihood	Comment
Not complete reconstitution	low	N/A
Contamination of the product during labelling	low	self-control is possible
Ligth protection	low	N/A
Storage of unlabelled product	low	N/A
Shelf life of the labelled product	low	N/A
Eluent	possible	N/A
Overdose /Underdose	possible	N/A
Wrong root of administration	low	N/A
Product mix-up	low	N/A
Premedication of the patient	low	patient consenting needed
Non fasting patient	possible	patient consenting needed

Drug interaction	possible	patient consenting needed
Food interaction	possible	patient consenting needed

Potential for overdose/underdose -Possible.
Only qualified personnel working at the nuclear medicine departments –supervised by the Nuclear Safety Officer - can prepare and inject the diagnostic drug. Overdose is possible if the weight of the patient is not known precisely and so the amount of injected dose is not calculated well; if the injection was not complete; if the circulation in an impaired tissue is slowed down so the dose cumulates somewhere in the body.

Potential for transmission of infectious agents – Not relevant
Possible. The drug is prepared in situ at the nuclear medicine departments only in appointed sites according to the local and international Quality Assurance Guidelines, like ISO. The aseptic preparation is an essential requirement regulated by the Good Radiopharmaceutical Pharmacy Pract

Potential for misuse for illegal purposes - Not relevant.

Potential for off-label use - Not relevant.

Potential for off-label-paediatric use -Not relevant

Disposal of the preparation:
The hospital pharmacists are trained on storage and disposal of these preparations. They follow the international standards and guidelines on disposal of radioactive preparations.

Reporting obligations
The qualified users working at the nuclear medicine departments are of key importance when using the kits as for: the preparation and dosing of these diagnostic kits; they are the primary contact for the patients so they should consent the patients and they should collect the information about them.
They should be aware of the reporting obligations.

The MAH is committed to collect data on their products and review the package leaflet continuously.
The MAH makes an internal review quality control of the reported cases and every 6 months.

This medicine has no additional risk minimisation measures.