

VI.2 Elements for a Public Summary

VI.2.1 *Overview of disease epidemiology*

Breast Cancer

Breast cancer is the most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012 (second most common cancer overall). This represents about 12% of all new cancer cases and 25% of all cancers in women. Eight to ten women are suffering from breast cancer in their lifetime. The average age of diagnosing breast cancer lies between 60 and 65 years. The mortality of breast cancer is dropping, while the incidence (number of new cases) is rising. Breast cancer is the most common cancer and the leading cause of death in women worldwide. Although breast cancer occurs mainly in women one in a hundred of tumours in the breast occur in men.

Malignant Melanoma

Malignant melanoma or skin cancer is a highly malignant tumor of the pigment cells (melanocytes). It tends to spread early and metastases grow via lymphatic and blood vessels. Malignant Melanoma is the most common fatal skin disease with worldwide strongly rising number of new cases. The number of melanoma cases worldwide is increasing faster than any other cancer. The annual increase in incidence rate varies between populations, but in general has been in the order of 3-7% per year for fair-skinned populations. The mean age of women was 58 and of men 64 years.

VI.2.2 *Summary of treatment benefits*

Sentinel lymph nodes in tumor diseases (Sentinel Node Mapping)

Breast cancer and malignant melanoma spread through the lymphatic system, and one of the earliest sites of spread for these cancers are nearby lymph nodes (sentinel lymph node/s). Once the sentinel lymph node is located, the surgeon makes a small incision in the overlying skin and removes the node. This so called sentinel lymph node biopsy (SLNB) helps doctors in staging cancers and to estimate the risk that tumor cells have developed the ability to spread to other parts of the body. Removing additional nearby lymph nodes to look for cancer cells may not be necessary if the sentinel node is negative for cancer. For this reason SLNB may help patients without a metastasising primary tumour to avoid dissection of additional lymph nodes. An extended lymph node surgery can have adverse effects, and some of these effects, like pain and immobility of shoulder and arms may be reduced or avoided. The length of hospital stay may be reduced and a better quality of life is evidenced. Patients can return earlier to normal day to day activities.

The integrity of the lymphatic system and differentiation of venous from lymphatic obstruction

Lymphoedema is, in the untreated state, a progressive, chronic disease as a result of primary or secondary damage to the lymphatic system with consecutive increase and change in the interstitial fluid. Lymphoscintigraphy has the highest diagnostic value in the examination of lymphoedema.

Bone marrow scans and inflammatory conditions

Many diseases of the bones and the blood cells have its origin in the bone marrow. This means that an early examination of the bone marrow can indicate diseases (e.g. malignant lymphoma, tumours of the bones and unspecified inflammations) in very early stages.

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 and potential identified risks

Risk	What is known	Preventability
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 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 to 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.
Hypersensitivity reaction	Like all medicines, 99m Technetium nanocolloids 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	02.07.2010	<ul style="list-style-type: none">• Carcinogenicity and hereditary effects• Hypersensitivity reactions	Initial Version