VI.2 Elements for a Public Summary

Sentinel node biopsy is a surgical procedure used to determine if cancer has spread beyond a primary tumor into your lymphatic system. Sentinel node biopsy is used most commonly in evaluating breast cancer and melanoma.
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The sentinel nodes are the first few lymph nodes into which a tumor drains. Sentinel node biopsy involves injecting 99mTc-NanoScan that helps the surgeon locate the sentinel nodes during surgery. The sentinel nodes are removed and analyzed in a laboratory. If the sentinel nodes are free of cancer, then cancer isn't likely to have spread and removing additional lymph nodes is unnecessary.

If, after sentinel node biopsy, evaluation of the sentinel nodes reveals cancer, then you'll likely need additional lymph nodes removed for your doctor to determine how far the cancer has spread.

VI.2.2 Summary of treatment benefits

Sentinel node biopsy is recommended for people with certain types of cancer in order to determine whether the cancer cells have migrated into the lymphatic system.
Sentinel node biopsy is routinely used for people with:
- Breast cancer
- Melanoma

The determinantion of the location and stage of the disease is pivotal for the future therapy of the patient. The lymphatic system and differentiation of the venous and lymphatic obstructions with the aid of conventional lymphoscintigraphy is important. The location of the sentinel lymph nodes can also be found. Sentinel lymph node localization and its successive biopsy represent one of the most important developments for the management of infiltrated early breast cancer.
The development and routine applications of new diagnostic techniques have contributed to detect the disease in early stage which allows decreasing the possibility of auxlillary tumoral infiltration.
Lymphoscintigraphy technique has shown to be safe and efficient method to identify and analyse the first, the sentinel node of the lymphatic drainage from the tumor.
After reconstitution of NanoScan with 99mTc solution and injecting it s the patient the imaging of the tumor will be possible by the aid of a scintigraphy technique.
Reconstitution of NanoScan is prepared at the nuclear medicine departments under the supervision of the qualified personnel. The use of the diagnostic it sin 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)
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.
interaction with iodinated contract	Iodinated contrast media used may interfere with lymphatic scanning and alter the test results. Such as iodine containing antiseptics.

Risk	What is known (Including reason why it is considered a potential risk)
media	

Important missing information

Risk	What is known
safety in patients with renal impairment	The following relevant information are known with limited background information about the incidence, prevalence, mortality and demographic profile of the target population of these diseases.
safety in patients with hepatic impairment	The following relevant information are known with limited background information about the incidence, prevalence, mortality and demographic profile of the target population of these diseases.
use in children	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.
use in pregnancy & breast feeding	The following relevant information are known with limited background information about the incidence, prevalence, mortality and demographic profile of the target population of these diseases.

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.