Package leaflet: Information for patients NanoSPECT 0.5 mg,

radiopharmaceutical preparation kit

Technetium (^{99m}Tc)-labelled nano colloidal albumin.

Read the leaflet carefully before use as it contains important information for the patient.
- Keep this leaflet to be able to read it again if necessary.
- If in any doubt, ask the nuclear medicine physician supervising the procedure.
- If you experience any side effects, including any side effects not mentioned in this leaflet, tell the nuclear medicine physician who will
  will be supervising the procedure. See section 4.

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1. What NanoSPECT is and what it is used for
The drug is a radiopharmaceutical intended exclusively for diagnostic purposes. NanoSPECT should be labelled with technetium (^{99m}Tc) and the resulting product is used for diagnostic scintigraphy and evaluation:
- bone marrow
- inflammatory conditions
- state of the lymphatic system and in the differential diagnosis of venous and lymphatic stasis
- sentinel nodes in cancer (sentinel node mapping in melanoma, breast cancer, prostate cancer, penile cancer, oral squamous cell carcinoma and vulvar cancer).

The use of NanoSPECT results in exposure to a small dose of radioactivity. The treating physician and the nuclear medicine physician have considered the clinical benefits to the patient of performing the examination with a radiopharmaceutical product and have concluded that these outweigh the risks associated with radiation exposure.

2. Information important before using NanoSPECT

When not to use NanoSPECT:
- If the patient is allergic to nano colloidal human albumin or to any of the other ingredients of this medicine (listed in section 6).
- During pregnancy if the lymphoscintigraphy involves the pelvic region.

Scintigraphy is not recommended if there is complete lymphatic obstruction due to the risk of radiation necrosis at the injection site.

Warnings and precautions
When to take special care with NanoSPECT
- if you are pregnant or suspect that you may be pregnant
- if you are breast-feeding
- if you have kidney or liver disease

In these cases you should inform your nuclear medicine doctor. Your doctor
The nuclear medicine physician will inform the patient of the need to take special precautions after the administration of this medicine. If you have any further questions, please contact your nuclear medicine physician.

Important information before the administration of NanoSPECT
Drink plenty of water before the study so that you can urinate as often as possible in the first few hours after the study.

Children and adolescents
Please inform your nuclear medicine physician if you are under 18 years of age.

Medicines derived from human blood or plasma
When medicines are manufactured from human blood or plasma, a number of measures are taken to prevent the transmission of infectious agents to patients. These include:
- careful selection of blood and plasma donors to exclude donors who are at risk of transmitting infection,
- testing each donation and plasma pool for the presence of viruses or infection,
- the use of blood or plasma treatment steps to inactivate or remove viruses.

Nevertheless, if drugs made from human blood or plasma are used, it is not possible to completely eliminate the risk of transmission of infectious agents. This also applies to new, unknown viruses and other infectious agents.
There are no reports of viral infections being transmitted with albumin produced according to the requirements described in the European Pharmacopoeia and documented processes.
It is strongly recommended that each time a dose of NanoSPECT is administered to a patient the name and batch number of the drug should be recorded so that there is a record of the batches administered.

NanoSPECT and other medicines
Iodine-containing contrast agents used during lymphoangiography (a type of X-ray) may interfere with technetium (^{99m}Tc)-labelled nano colloidal albumin lymphoscintigraphy (NanoSPECT).

Tell your nuclear medicine physician about all medicines you are currently or recently, as well as any medication you plan to take, as these may interfere with the interpretation of the images.

If scintigraphy of the lymphatic system is required, the doctor should first be informed of any previous X-ray or contrast agent studies, as these may affect the test result.

A nuclear medicine physician should be consulted before using any medication.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, suspect that you may be pregnant or if you are planning to have a baby, you should advise your nuclear medicine physician before administering this medicine.

It is imperative that you inform your nuclear medicine physician before administering NanoSPECT if you suspect that you may be pregnant, have delayed menstruation or are breastfeeding.

It is important to speak to the nuclear medicine physician supervising the procedure if in doubt.

<u>If the patient is pregnant:</u>
NanoSPECT should not be used during pregnancy.

If the patient is breastfeeding:
If the patient is breastfeeding, inform the nuclear medicine physician, who will recommend that breastfeeding be discontinued until the radioactivity has been removed from the body. This takes approximately 24 hours. The extracted milk should be disposed of. Ask your nuclear medicine doctor when breastfeeding can be resumed.

Driving and operating machinery
NanoSPECT is unlikely to affect the ability to drive or operate machinery.

NanoSPECT contains sodium
The medicinal product contains less than 1 mmol of sodium (23 mg) per vial, i.e. the drug is considered 'sodium free'.

3. How to use NanoSPECT

Strict regulations regarding the use, disposal and handling of radiopharmaceutical products apply. NanoSPECT is only used in areas where there is a special control. Only persons trained and qualified in the safe use may come into contact with and administer the drug. These persons shall exercise extreme caution, to ensure the safe use of the medicine, and will inform the patient of their actions.
The nuclear medicine doctor overseeing the procedure will decide what dose of NanoSPECT drug should be administered in each case. This will be the lowest dose necessary to obtain the information needed.
The recommended dose typically administered to adults ranges from 5 to 500 MBq (megabecquerels, which is a unit of radioactivity) and is determined by the patient's body weight and the type of test being performed.
No dose reduction is necessary in patients with renal or hepatic impairment.

Use in children and adolescents
In children and adolescents, the dose administered will be adjusted according to the child's body weight.

Administration of NanoSPECT and procedure
NanoSPECT is administered intravenously (in a single injection) or subcutaneously after labelling (into one or more injection sites).
The drug is not intended for regular or continuous administration.
After the injection, the patient will be given a drink to drink and will be asked to urinate immediately before the test.

Duration of the procedure
The nuclear medicine physician will inform the patient of the typical duration of the procedure.

After the administration of NanoSPECT:
- close contact with young children and pregnant women should be avoided for 24 hours after administration
- urinate frequently to remove and eliminate the drug from the body

The nuclear medicine physician will inform the patient of the need to take special precautions after administration of this drug. If you have further questions, ask your nuclear medicine doctor.

Taking more than the recommended dose of NanoSPECT
An overdose is almost impossible because the patient receives only one dose of NanoSPECT, closely monitored by the nuclear medicine physician supervising the procedure.
However, in case of an overdose, appropriate treatment will be implemented.

In particular, the nuclear medicine physician in charge of the procedure may recommend drinking plenty of fluids to facilitate the removal of NanoSPECT from the body.
If you have any doubts about the use of NanoSPECT, please ask the nuclear medicine physician supervising the procedure.

4. Possible side effects

Like all medicines, this medicine may cause side effects, although not everyone will experience them.
The following incidence categories are used to assess adverse reactions:

Very common:	occur in more than 1 patient in 10
Frequent:	occur in 1 to 10 patients in 100
Uncommon:	occurs in 1 to 10 patients per 1000
Rare:	occur 1 to 10 patients per 10 000
Very rare:	occur in less than 1 patient per 10 000
Unknown:	frequency cannot be determined from the available data

Very rare:
slight and transient hypersensitivity reactions, with the following symptoms:
application site/skin:
local reactions, rash, itching
immune system disorders:
dizziness, decreased blood pressure

If a radiopharmaceutical product containing protein, such as NanoSPECT, is administered to a patient, hypersensitivity reactions may occur, including the very rare and life-threatening anaphylaxis, the frequency of which is unknown.

This radiopharmaceutical product results in exposure to a low dose of ionising radiation causing a low risk of cancer and birth defects in the foetus.

Reporting of adverse reactions
If you experience any side effects, including any side effects not listed in this leaflet, tell your nuclear medicine physician.
Adverse reactions can also be reported directly through the national reporting system listed to the Adverse Drug Reactions Monitoring Department of the
Office for Registration of Medicinal Products, Medical Devices and Biocidal Products,
Al. Jerozolimskie 181C
PL-02 222 Warsaw
Tel:+ 48 22 49 21 301
Fax:+ 48 22 49 21 309
Website: https://smz.ezdrowie.gov.pl
Adverse reactions may also be reported to the responsible entity.
By reporting side effects, more information on the safety of the medicine can be gathered.

5. How to store NanoSPECT

This medicine is not stored by the patient. It is stored under specialist supervision in a suitable place.
Radiopharmaceuticals should be stored in accordance with national regulations for radioactive materials.
The following information is intended for medical personnel only.
NanoSPECT must not be used after the expiry date on the label. The expiry date means the last day of the month stated.

Storage conditions
There are no special storage temperature requirements for this medicine.

Shelf life after first opening and radioisotope labelling
After radioisotope labelling: 12 hours. There are no special requirements for the storage temperature of this medicine after radioisotope labelling.
The ready-to-use suspension for injection must be stored in accordance with national regulations for radioactive materials.

Chemically and physically, the product is stable for 12 hours at 25 °C. From a microbiological point of view, as long as the method of opening/radiolabelling/dilution does not exclude the risk of microbiological contamination, the product should be used immediately.
If not used immediately, the user is responsible for the storage time and conditions during use.

6. Contents of the package and other information

What does NanoSPECT contain?
The active substance is human albumin, nano colloid. One vial contains 0.5 mg of nano colloid human albumin.

Other ingredients:
Tin(II) chloride dihydrate
Glucose
Poloxamer 238
Disodium phosphate dihydrate
Sodium phytate
Hydrochloric acid
Sodium hydroxide

What NanoSPECT looks like and what it contains in the pack
The drug is a kit for the preparation of a radiopharmaceutical preparation.
Each vial contains a white or whitish lyophilizate for preparing a suspension for injection.
When the radioactive substance, sodium pertechnetate (^{99m}Tc), is added to the vial, nano colloids of technetium (^{99m}) Tc)-labelled albumin are formed. The suspension is ready for injection. The package contains 5 10 ml glass vials in a cardboard box.

Marketing authorisation holder and manufacturer
ROTOP Pharmaka GmbH
Bautzner Landstrasse 400
01328 Dresden
Germany
Tel: +49 351 - 26 310 100
Fax: +49 351 - 26 310 303
E-mail: service@rotop-pharmaka.de

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The following information is intended for professional medical personnel only:
The full SmPC of the NanoSPECT medicinal *product is included in the product package as a separate document, so that professional medical personnel have access to additional scientific and practical information on the administration and use of this radiopharmaceutical product.*
Please refer to the content of the SmPC.

Other sources of information
Detailed information on this medicine is available on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products: www.urpl.gov.pl.