Package leaflet: Information for the patient

NANOCIS 0.24 mg kit for radiopharmaceutical preparation
rhenium sulphide

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What NANOCIS is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Nanocis contains the active substance rhenium sulphide.
This product should be mixed with a radioactive solution of 'technetium-99m' and the obtained solution of technetium (^{99m}Tc) colloidal rhenium sulphide is used for scintigraphic imaging in adults and children.

Because the substance contains a small amount of radioactivity, it can be detected from outside the body using special cameras, and pictures, known as scans, can be taken. These scans will give your physician informations about your pathology.

NANOCIS is used in lymphography and digestive exploration (gastroesophageal scintigraphy).

The use of Nanocis does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before you are given NANOCIS

You must not be given NANOCIS

- if you are allergic to rhenium sulphide or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions

Take special care with NANOCIS
Please tell your doctor in the following cases:

- If you are pregnant or think you might be pregnant.
- If you are breast-feeding,
- If you have an allergic disease, because some cases of allergic type reactions have been reported after administration of technetium (^{99m}Tc) colloidal rhenium sulphide.
- If you have a complete block of the lymphatic system because in this case, lymphoscintigraphy is not advised.

Your nuclear medicine doctor will inform you if you need to take any special precautions in those cases.

Technetium (^{99m}Tc) colloidal rhenium sulphide solution is administered by people who are trained and qualified in the safe handling of radioactive material.

Children and adolescents
Talk to your nuclear medicine doctor if you are or your child is under 18 years old.

Other medicines and NANOCIS
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, since they may interfere with the interpretation of the images. For example, anaesthetic agents or hyaluronidase.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of Nanocis if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.
When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant
The nuclear medicine doctor will only administer Nanocis during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding:
Tell your nuclear medicine doctor if you are breast-feeding as he/she may delay the investigation until breast-feeding is completed or ask you to stop breast-feeding for a short while until the radioactivity has left your body. This takes about 24 hours. The expressed milk should be discarded.
Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines
It is considered unlikely that Nanocis will affect your ability to drive or to use machines.

Nanocis contains sodium
This medicine contains less than 1 mmol of sodium (23 mg) per administration, that is to say essentially 'sodium-free'.

3. How will you be given NANOCIS

How much Nanocis is given:
Your physician will decide on the amount of technetium (^{99m}Tc) colloidal rhenium sulphide to be used.

Lymphography:
The dosage of technetium (^{99m}Tc) colloidal rhenium sulphide injection to an adult is 18.5-185 MBq. The amount of radiopharmaceutical is usually below 20 MBq per injection site, depending on the anatomical areas to be investigated and the time interval between injection. The dose per injection site can be reduced in children, but a minimum dose of about 5-10 MBq per injection site is necessary to obtain images of sufficient quality.

Digestive exploration:
For adults and children, an oral dosage of 3.7 to 11.1 MBq of technetium (^{99m}Tc) colloidal rhenium sulphide (other doses may be justifiable) can be given in a liquid phase in accordance with local practice.

How Nanocis is given
Lymphography: technetium (^{99m}Tc) colloidal rhenium sulphide solution is given by single or multiple subcutaneous (interstitial) injection(s).

Digestive exploration: technetium (^{99m}Tc) colloidal rhenium sulphide solution is given orally in a liquid phase according to local practice.

Scanning can be started immediately after injection.

If you are given too much NANOCIS
Since Nanocis is administered by a physician under strictly controlled conditions there is little chance of possible radiation overdose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In some cases, administration of the product can involve allergic side effects.
The injection of the hypertonic technetium (^{99m}Tc) colloidal rhenium sulphide solution can produce pain at the injection site.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: http://www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How NANOCIS is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

6. Contents of the pack and other information

What NANOCIS contains

- The active substance is rhenium sulphide (0.24 mg/vial A).
- The other ingredients are:

Vial A: gelatin, ascorbic acid, sodium hydroxide, concentrated hydrochloric acid, water for injections under nitrogen atmosphere.

Vial B: stannous chloride dihydrate, sodium pyrophosphate decahydrate, concentrated hydrochloric acid, sodium hydroxide, under nitrogen atmosphere.

What NANOCIS looks like and contents of the pack

NANOCIS is a radiopharmaceutical kit, composed of two vials, A & B. A quantity of B and A are mixed together prior to radiolabelling with a solution of sodium pertechnetate (^{99m}Tc) to form technetium (^{99m}Tc) colloidal rhenium sulphide.
Vial A: Dark brown colloidal solution. Vial B: White freeze-dried powder

Pack size: The kit contains 5 vials A and 5 vials B.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the HPRA website.

The following information is intended for healthcare professionals only:

The complete SmPC of Nanocis is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC included in the box.