PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Technescan MIBI 1 mg, kit for radiopharmaceutical preparation

[Tetrakis(2-methoxy-2-methylpropyl-1 isocyanide)copper(I)] tetrafluoroborate

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 TECHNESCAN MIBI IS AND WHAT IT IS USED FOR

This medicine is a radiopharmaceutical product for diagnostic use only.

Technescan MIBI contains a substance called [tetrakis(1-isocyanide-2-methoxy-2-methylpropy)copper(I)] tetrafluoroborate which is used to study the heart function and blood flow (myocardial perfusion) by making an image of the heart (scintigraphy), for example in the detection of heart attacks (myocardial infarctions) or when a disease causes reduced blood supply to (a part of) the heart muscle (ischaemia). Technescan MIBI is also used in the diagnosis of breast abnormalities in addition to other diagnostic methods when the results are unclear. Technescan MIBI can also be used to find the position of overactive parathyroid glands (glands that secrete the hormone that controls blood calcium levels).

After Technescan MIBI is injected, it temporarily collects in certain parts of the body. This radiopharmaceutical substance contains a small amount of radioactivity, which can be detected from outside of the body by using special cameras. Your nuclear medicine doctor will then take an image (scintigraphy) of the concerned organ which can give your doctor valuable information about the structure and the function of this organ or the location of e.g., a tumour.

The use of Technescan MIBI 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 TECHNESCAN MIBI IS USED

Technescan MIBI must not be used
- if you are allergic to tetrakis (1 isocyanide-2-methoxy-2-methylpropyl-) copper(I)] tetrafluoroborate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Take special care with Technescan MIBI

- if you are pregnant or believe you may be pregnant,
- if you are breastfeeding,
- if you have a kidney or liver disease.

You should inform your nuclear medicine doctor in case those apply to you. Your nuclear medicine doctor will inform you if you need to take any special precautions after using this medicine. Talk to your nuclear medicine doctor if you have any questions.

Before administration of Technescan MIBI you should
- be fasting for at least 4 hours if the product is going to be used to perform images of your heart,
- drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study.

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

Other medicines and Technescan MIBI
A number of medicines, foods and beverages can adversely affect the outcome of the planned investigation. It is therefore recommended to discuss with the referring physician, which intake should be discontinued before the investigation and when the medicines should be taken again. Tell also your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, since they may interfere with the interpretation of the images.
Especially tell your nuclear medicine doctor if you are taking:
- medicines which affect heart function and/or blood flow.
- medicines which are called proton pump inhibitors. They are used to reduce stomach acid production, such as omeprazole, esomeprazole, lansoprazole, rabeprazole, pantoprazole, dexlansoprazole.

Please ask your nuclear medicine doctor before taking any medicines.

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

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

If you are breastfeeding,
please tell your nuclear medicine doctor, as he/she may advise you to stop doing so 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 breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before taking this medicine.

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

Technescan MIBI contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially ‘sodium- free’.

3. HOW TECHNESCAN MIBI IS USED

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Technescan MIBI will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Technescan MIBI to be used in your case. It will be the smallest quantity necessary to get the desired information.
The quantity usually recommended to be administered for an adult ranges depending on the test to be performed, and ranges between 200 and 2000 MBq (Megabecquerel, the unit used to express radioactivity).

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Administration of Technescan MIBI and conduct of the procedure
Technescan MIBI is administered in a vein of the arm or the foot (intravenous administration). One to two injections is sufficient to conduct the test that your doctor needs.
After injection, you will be offered a drink and asked to urinate immediately preceding the test.
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.
The ready-to-use solution will be injected to you in a vein before the scintigraphy is taken. The scanning may take place within 5 to 10 minutes or up to 6 hours after injection, depending on the test.

In the case of a heart investigation, two injections may be necessary, one at rest and one at stress (e.g., during a physical exercise or pharmacological stress). The two injections will be done at least two hours apart and not more than 2000 MBq in total (1 day protocol) will be administered. A two day protocol is feasible, also.

For the scintigraphy of breast abnormalities, an injection of 750 to 1100 MBq is administered into a vein of your arm opposite to the breast concerned, or into a vein of your foot.

To find the position of overactive parathyroid glands, the activity administered is between 185 and 1100 MBq, depending on the methods used.

If the medicine is going to be used to perform images of your heart, then you will be asked not to eat anything for at least 4 hours before the test. After the injection, but before the image (scintigraphy) is made, you will be asked to eat a light fatty meal, if possible, or to drink one or two glasses of milk in order to decrease the radioactivity in your liver and to improve the image.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of Technescan MIBI has been performed, you should:
- avoid any close contact with young children and pregnant women for the 24 hours following the injection,
- urinate frequently in order to eliminate the product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more Technescan MIBI than you should
An overdose is almost impossible because you will only receive a dose of Technescan MIBI precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the

procedure may recommend that you drink abundantly in order to facilitate the elimination of Technescan MIBI from your body.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine doctor who supervises the procedure.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Allergic reactions possibly with shortness of breath, extreme tiredness, being sick (usually within 2 hours after administration), swelling beneath the skin that can occur in areas such as the face and limbs (angioedema), and obstruct the airway, or leading to a dangerous decrease of blood pressure (hypotension) and slow heart beat (bradycardia) have been seen rarely. Doctors are aware of this possibility and have emergency treatment available for use in such cases. Local skin reactions have also been seen rarely with itching, hives, rash, swelling and redness. If you experience any of those, please refer immediately to your nuclear medicine doctor.

Other possible side effects are listed in the order of their frequency below:

Frequency	Possible side effects
common: may affect up to 1 in 10 people	Metallic or bitter taste, smell alteration, and dry mouth immediately after injection.
uncommon: may affect up to 1 in 100 people	Headache, chest pain, abnormal ECG and feeling sick.
rare: may affect up to 1 in 1,000 people	abnormal heart rhythm, local reactions at the injection site, stomach ache, fever, fainting, seizures, dizziness, flushing, skin numbness or tingling, tiredness, joint pains and stomach upset (dyspepsia).
not known: frequency cannot be estimated from the available data	Erythema multiforme, a widespread rash of skin and mucosa.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TECHNESCAN MIBI 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.

The following information is intended for the specialist only.

This medicine must not be used after the expiry date, which is stated on the label.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Technescan MIBI contains

- The active substance is [Tetrakis(2-methoxy-2-methylpropyl-1 isocyanide)copper(I)] tetrafluoroborate.
- One vial contains 1 mg [Tetrakis(2-methoxy-2-methylpropyl-1 isocyanide)copper(I)] tetrafluoroborate.

The other ingredients are stannous chloride dihydrate, cysteine hydrochloride monohydrate, sodium citrate, mannitol, hydrochloric acid and sodium hydroxide.

What Technescan MIBI looks like and contents of the pack

The product is a kit for radiopharmaceutical preparation.

Technescan MIBI consists of white to almost white pellets or powder which has to be dissolved in a solution and combined with radioactive technetium before use as an injection. Once the radioactive substance sodium pertechnetate (^{99m}Tc) is added to the vial, technetium (^{99m}Tc) sestamibi is formed. This solution is ready for injection.

Pack size
5 multi-dose vials

Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.
Westerduinweg 3
1755 LE PETTEN, The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Technescan Sestamibi
Belgium	Technescan Sestamibi
Bulgaria	Technescan Sestamibi
Cyprus	Technescan Sestamibi
Czech Republic	Technescan Sestamibi
Germany	Technescan Sestamibi
Denmark	Technescan Sestamibi
Estonia	Technescan Sestamibi
Greece	Technescan Sestamibi
Spain	MIBI Technescan
Finland	Technescan Sestamibi
France	Technescan Sestamibi
Hungary	Technescan Sestamibi
Ireland	Technescan MIBI
Italy	Technemibi
Lithuania	Technescan Sestamibi
Luxembourg	Technescan Sestamibi
Latvia	Technescan Sestamibi
Malta	Technescan MIBI
Netherlands	Technescan Sestamibi
Norway	Technescan Sestamibi

Portugal	Technescan Sestamibi
Romania	Technescan Sestamibi
Sweden	Technescan Sestamibi
Slovenia	Technescan Sestamibi
Slovak Republic	Technescan Sestamibi
United Kingdom	Technescan MIBI

This leaflet was last revised in June 2021.

The following information is intended for healthcare professionals only:
[Note: It is intended to include the SmPC]