

Package leaflet: Information for the patient

TechneScan MAG3 1mg kit for radiopharmaceutical preparation

betiatide

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.

What is in this leaflet

1. What TechneScan MAG3 is and what it is used for
2. What you need to know before TechneScan MAG3 is used
3. How TechneScan MAG3 is used
4. Possible side effects
5. How TechneScan MAG3 is stored
6. Contents of the pack and other information

1. What TechneScan MAG3 is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

TechneScan MAG3 is used through a scan to examine the:

- kidneys,
- urine output and
- bladder.

This medicine is a powder. When mixed by qualified people, with a solution of the radioactive substance, sodium pertechnetate (^{99m}Tc), it forms technetium(^{99m}Tc) mertiatide. When injected into the body it collects in certain organs such as, the kidneys.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the organ and body. This also gives the doctor valuable information about the structure and function of that organ.

The use of TechneScan MAG3 in combination with sodium pertechnetate (^{99m}Tc) 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 MAG3 is used

TechneScan MAG3 must not be used:

- if you are allergic to betiatide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your nuclear medicine doctor before you are given TechneScan MAG3

- if you are pregnant or believe you may be pregnant
- if you are breast feeding

Before TechneScan MAG3 administration you should

- 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 MAG3

Tell your nuclear medicine doctor if you are taking or have recently taken or might take any other medicines since they may interfere with the interpretation of the images.

TechneScan MAG3 is known to influence or be influenced by some other medicines such as acetylsalicylic acid, contrast media, probenecid, hydrochlorothiazide, NSAIDs such as diclofenac, sulfonamides and calcium antagonist.

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 nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of TechneScan MAG, 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 this product during pregnancy if a benefit is expected which would outweigh the risks.

• If you are breast-feeding

The doctor may delay the examination until you stop breast-feeding. If this not possible, your doctor will ask you to stop breast-feeding for 4 hours and discard the expressed breastmilk during this period.

You do not need to avoid close contact with your baby after the procedure.

Driving and using machines

It is considered unlikely that TechneScan MAG3 will affect your ability to drive or to use machines.

TechneScan MAG3 contains sodium

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

3. How TechneScan MAG3 is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. TechneScan MAG3 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 MAG3 and sodium pertechnetate (^{99m}Tc) to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity of sodium pertechnetate (^{99m}Tc) to be administered usually recommended for an adult range from 40-200 MBq (megabecquerel, the unit used to express radioactivity).

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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 MAG3 and conduct of the procedure

Technescan MAG3 is administered by intravenous injection.

One injection of Technescan MAG3 is sufficient to conduct the test that your doctor needs.

Duration of the procedure

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

After administration of Technescan MAG3, you should

- drink a lot of water to urinate frequently and 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 MAG3 than you should

An overdose is unlikely because you will only receive a single dose of Technescan MAG3 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 plenty of water and urinate frequently to remove the traces of radioactivity from your body.

Should you have any further question on the use of Technescan MAG3, 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.

Side effects with frequency not known (cannot be estimated from the available data):

- **Allergic reactions** including sudden, severe allergic reactions, with symptoms such as itchy rash, swelling of eyelids, cough, feeling sick, vomiting.
- **Circulatory reactions** with symptoms such as seizure, difficulty in breathing, reddening of the skin, headache, facial swelling, pain, abnormal sensation, sensation of unsteadiness, low blood pressure, rapid heartbeat.
- **Injection site reactions** with symptoms such as skin rash, pain, swelling.

This radiopharmaceutical product 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.

HPRA Pharmacovigilance

Website: www.imbhpra.ie

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

5. How Technescan MAG3 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.

- Technescan MAG3 must not be used after the expiry date which is stated on the label after "EXP".
- Technescan MAG3 must not be used if there are visible signs of deterioration.

6. Contents of the pack and other information

What Technescan MAG3 contains

- The active substance is betiatide.
One vial contains 1 mg betiatide.
- The other ingredients are disodium tartrate dihydrate, stannous chloride dihydrate, hydrochloric acid.

What Technescan MAG3 looks like and contents of the pack

Technescan MAG3 contains a powder, packed in a 10 ml type I glass vial with a rubber stopper and closed with an aluminium cap. Pack size: 5 vials.

Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.

Westerduinweg 3

1755 LE Petten

The Netherlands

This leaflet was last revised in 12/2023.

The following information is intended for medical or healthcare professionals only:

The complete Summary of Product Characteristics (SmPC) of Technescan MAG3 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 of Technescan MAG3.

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