

TechneScan® MAG3

Kit for radiopharmaceutical preparation
powder for solution for injection

betiatide

Read all of this leaflet carefully before you start using 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 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:

- **kidney function**

The use of TechneScan MAG3 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.

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] tiateide. 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.

2. What you need to know before TechneScan MAG3 is used

TechneScan MAG3 must not be used

if you are

- **allergic (hypersensitive) to betiatide or any of the other ingredients**

Warnings and precautions

Take special care with 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 administration in order to urinate as often as possible during the first hours after the study

Children and adolescents

Please speak to your Nuclear medicine doctor if you are under 18 years old.

Using other medicines

Please tell your Nuclear medicine doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription since they may interfere with the interpretation of the images.

The following medicines can influence or be influenced by TechneScan MAG3:

- Contrastmedia

Pregnancy, breast-feeding and fertility

You must inform the Nuclear medicine doctor before the administration of TechneScan MAG3 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 TechneScan MAG3 during **pregnancy if a benefit is expected which would outweigh the risks.**

If you are breast-feeding

Tell your doctor if you are breast-feeding as he may **delay treatment** until breast-feeding is finished. He may also ask you to **stop breast-feeding** and discard this milk, until the radioactivity is no longer in your body. Please ask your Nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of TechneScan MAG3

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. 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 to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult is **100 MBq** (Mega Becquerel, 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 MAG3 and conduct of the procedure

TechneScan MAG3 is administered by injection. One injection is usually sufficient to conduct the test that your doctor needs.

Duration of the procedure

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

After administration of TechneScan MAG3, you should:

urinate frequently in order to eliminate the product from your body.

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.

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, TechneScan MAG3 can cause side effects, although not everybody gets them.

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

Side effects can occur with the following frequencies:

very rare, occurs in fewer than 1 per 10,000 users:

- allergic reactions, with signs such as
 - flushes
 - skin rash
 - headache
 - nausea and vomiting
 - breathing difficulties
 - swelling of the face
 - pain
 - feeling unwell
- widening of blood vessels causing reduced blood pressure, fainting
- local reactions on the injection site

If you get any side effects talk to your Nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

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 will not be used:

- after the expiry date stated on the label
- if visible signs of deterioration are noticed

The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What TechneScan MAG3 contains

- The active substance is: betiatide
- The other ingredients are: disodium tartrate dihydrate, stannous chloride dihydrate and hydrochloric acid.

What TechneScan MAG3 looks like and contents of the pack

TechneScan MAG3 is a white powder for reconstitution. It is packaged in 10 ml glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

Pack size

TechneScan MAG3 is supplied in one pack that contains 5 vials.

Marketing Authorisation Holder and Manufacturer

Mallinckrodt Medical B.V.

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This leaflet was last approved in