

Technescan DMSA

1.2 mg kit for radiopharmaceutical preparation

Dimercaptosuccinic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information.

- 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.

In this leaflet:

1. What Technescan DMSA is and what it is used for
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1. What Technescan DMSA is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Technescan DMSA is used through a scan to examine the:

- kidneys

The use of Technescan DMSA 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 DMSA-[^{99m}Tc]technetium. When administered 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 gives the doctor valuable information about the structure and function of that organ.

2. What you need to know before Technescan DMSA is used

Technescan DMSA must not be used

- allergic (hypersensitive) to dimercaptosuccinic acid or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Take special care with Technescan DMSA

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

Before administration Technescan DMSA 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

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

Other medicines and Technescan DMSA

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

The following **medicines** can influence or be influenced by Technescan DMSA:

- **ammonium chloride**, (sal ammoniac, a substance present in some cough medicines and liquorice juice)
- **sodium bicarbonate**, (medicine administered to reduce the acidity of blood and/or urine)
- **mannitol**, (diuretic medicine)
- certain antihypertensive medicines (so called ACE inhibitors, like captopril, enalapril)
- anticancer medicines, (methotrexate, cyclophosphamide, vincristine)

Pregnancy, breast-feeding and fertility

You must inform the Nuclear medicine doctor before the administration of Technescan DMSA 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 DMSA 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 DMSA will affect your ability to drive or to use machines.

3. How Technescan DMSA is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Technescan DMSA 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 DMSA 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 ranges from 30 to 120 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 DMSA and conduct of the procedure

Technescan DMSA is administered by injection.

One injection is usually sufficient. After injection, you will be asked to drink and urinate as much as possible in order to prevent active substance gathering in the bladder.

Duration of the procedure

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

After administration of Technescan DMSA, you should:

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 DMSA than you should
An overdose is unlikely because you will only receive a single dose of Technescan DMSA precisely controlled by the Nuclear medicine doctor supervising the procedure. Drinking as much as possible, such as water, will help remove the radioactive substance more quickly.

Should you have any further question on the use of Technescan DMSA, please ask the Nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, Technescan DMSA can cause side effects, although not everybody gets them.

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

Side effects can occur with the following frequencies:

rare, occurs in 1 to 10 per 10,000 users

- allergic reactions

Hospital staff will treat these reactions, if they occur.

frequency unknown, from the data available

- cancer or hereditary defects are linked to radiation exposure
However, the risk is very low as low doses are used in this investigation.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By 16-APP-4341-Ireland-PIL-15052019_clean.doc

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

5. How Technescan DMSA 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 DMSA will not be used after the expiry date stated on the label.

Technescan DMSA will not be used if visible sign of deterioration are noticed.

6. Contents of the pack and other information

What Technescan DMSA contains

- The active substance is: dimercaptosuccinic acid.
- The other ingredients are: stannous chloride dihydrate, inositol, sodium hydroxide, hydrochloric acid

What Technescan DMSA looks like and contents of the pack

Technescan DMSA is a greyish white to slightly yellow pellet or powder. It is packaged in 10 ml colourless glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

It is supplied in one pack that contains 5 vials.

Marketing Authorisation Holder and Manufacturer

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The Netherlands

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