

# Technescan DMSA

1.2 mg kit for radiopharmaceutical preparation

succimer

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

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

This medicine is a radiopharmaceutical product for diagnostic use only. Technescan DMSA contains the active substance succimer. It is used for the preparation of a radioactive solution for injection of technetium (<sup>99m</sup>Tc) succimer.

Technescan DMSA is used in adults and children to examine the kidneys. When injected, this medicine temporarily collects in your kidneys. Because of its radioactivity, it can be detected outside the body using a special camera, and pictures, known as scans, can be taken. These scans give valuable information about the **structure and/or the functioning of your 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.

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

### Technescan DMSA must not be used

- if you are allergic to succimer or to any of the other ingredients of this medicine (listed in section 6), or to any of the ingredients of the radiolabelled product (technetium <sup>99m</sup>Tc succimer).

### Warnings and precautions

Take special care with Technescan DMSA

- if you are pregnant or believe you may be pregnant.
- if you are breast-feeding.
- If you have a kidney disease.

Please talk to your nuclear medicine doctor if any of the above applies to you. This medicine may not be suitable for you. Your nuclear medicine doctor will advise you.

### Before administration of Technescan DMSA 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 DMSA

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.

Your nuclear medicine doctor / doctor may recommend that you stop taking the following medicines before the procedure with Technescan DMSA:

- **ammonium chloride** (ammoniac salt, 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 which helps you make more urine and to lose salt and excess water from your body)
- certain **antihypertensive medicines** to treat high blood pressure (so called ACE inhibitors, like captopril)

Some anticancer medicines (methotrexate, cyclophosphamide, vincristine) might also influence or be influenced by Technescan DMSA.

### 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 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/she may **delay** the examination until breast-feeding is completed. He/she may also ask you to **stop breast-feeding for a short while** and discard the expressed breastmilk during this period, until the radioactivity is no longer in your body. Please ask your nuclear medicine doctor when you can resume breast-feeding.

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

### Driving and using machines

It is considered unlikely that Technescan DMSA will affect your ability to drive or to use machines.

### Technescan DMSA contains sodium

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

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### 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 technetium ( $^{99m}\text{Tc}$ ) succimer 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** (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, usually into a vein in your arm. One injection 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.

#### Duration of the procedure

The scans are usually taken 2 to 3 hours after injection. Occasionally, they may be delayed up to 24 hours after injection. Your nuclear medicine doctor will inform you about the 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. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor may recommend that you drink plenty of water and void frequently to remove the traces of radioactivity from your body.

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

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

- **Allergic reactions** with symptoms such as skin rashes, reddening or itching, increased sweating, swelling of the eyes, the tongue or the throat swelling, eye inflammation, cough, shortness of breath, nausea, vomiting, hypersalivation, belly ache, flushing or low blood pressure
- **Circulatory reactions** with symptoms such as fainting, low blood pressure, headache, dizziness, paleness, weakness or tiredness
- **Reactions at the injection site**, with symptoms such as skin rash, swelling, or inflammation

Hospital staff will treat these reactions, if they occur.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By 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 which is stated on the label after "EXP".

### 6. Contents of the pack and other information

#### What Technescan DMSA contains

- The active substance is succimer (or dimercaptosuccinic acid ). One vial contains 1.2 milligrams of succimer.
- The other ingredients are: inositol, stannous chloride dihydrate (E512), hydrochloric acid (E507), sodium hydroxide (E524).

#### What Technescan DMSA looks like and contents of the pack

Technescan DMSA is a kit for radiopharmaceutical preparation intended to be used by healthcare professionals only. Before it is used, the powder in the vial is mixed with a radioactive solution called technetium ( $^{99m}\text{Tc}$ ) to form a solution of technetium ( $^{99m}\text{Tc}$ ) succimer.

Technescan DMSA is packaged in a 10 ml colourless type I glass vial 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

Curium Netherlands B.V.  
Westerduinweg 3  
1755 LE Petten  
The Netherlands

#### This leaflet was last revised in .

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

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

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