

TechneScan DTPA

Kit for radiopharmaceutical preparation,

pentetic acid 20.8 mg

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

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

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

This medicine is a radiopharmaceutical for **diagnostic use only**.

TechneScan DTPA is used for scanning to examine:

- kidneys
- brain
- lungs
- **gastroesophagus reflux and gastric emptying**

This medicine is a non-radioactive powder. When mixed by qualified personnel, with a solution of the radioactive substance, sodium pertechnetate (^{99m}Tc) it forms Technetium [^{99m}Tc] pentetate. When administered into the body it collects in certain organs such as, the kidneys or the brain.

The radioactive substance can be photographed (scanned) from outside the body, using special cameras. 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 DTPA 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 do you need to know before Technescan DTPA is used

Technescan DTPA must not be used

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

Warnings and precautions

- You must not be given this medicine in the spinal canal and brain space, known as the subarachnoid space.

Take special care with TechneScan DTPA

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

Before administration of Technescan DTPA 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. This will prevent active substance gathering in the bladder.
- Tell your doctor if you have symptoms of decreased kidney function

Children and adolescents

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

Other medicines and Technescan DTPA

Tell your nuclear medicine doctor if you are taking or have recently taken or might take any other medicines.

The following **medicines** can specially interfere with the results of the examination with Technesacn DTPA.

- Medicines interfering with renal imaging:
 - medicines to treat high blood pressure, for example, medications with active substances with names ending in "pril", such as: captopril.
 - medicines that stimulate water clearance from the body, such as furosemide
- Medicines interfering with brain imaging
 - medicines which influence mood, emotional status and disposition

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 doctor for advice before taking this medicine.

You must inform the nuclear medicine doctor before the administration of Technescan DTPA 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

Your nuclear medicine doctor will only administer Technescan DTPA during pregnancy if a benefit is expected which would outweigh the risks to the unborn child.

- If you are breast-feeding

Tell your doctor if you are breast-feeding as he/she may **delay the study** until breast-feeding is finished. Your doctor may also ask you to **stop breast-feeding for 12 hours** 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 DTPA will affect the ability to drive and use machines.

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3. How Technescan DTPA is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Technescan DTPA will only be used in special controlled settings (hospital or similar). 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 DTPA to be used in your case. The dose administered will depend on the procedure you are undergoing and other factors such as the kind of administration. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an **adult** ranges from 7 to 1000 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 according to the child's weight.

Administration of Technescan DTPA and conduct of the procedure

Technescan DTPA is injected into a vein for imaging the kidneys or the brain, is taken orally for stomach or oesophagus investigations and is inhaled for lung examinations. A single administration is usually sufficient.

Duration of the procedure

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

After administration of Technescan DTPA, 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 DTPA than you should

An overdose is unlikely because you will only receive a single dose of Technescan DTPA precisely controlled by the nuclear medicine doctor supervising the procedure. However, in case of an overdose you will receive the appropriate treatment.

Drinking as much as possible, such as water, will help remove the radioactive substance more quickly.

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

4. Possible side effects

Like all medicines, TechneScan DTPA can cause side effects, although not everybody gets them.

The following Side effects can occur. The frequency of occurrence cannot be estimated from the available data.

- Widening of the blood vessels which cause sudden redness of the skin,
- dizziness
- shortness of breath (dyspnoea)
- itchiness
- hives (urticaria)
- lowered blood pressure (hypotension).

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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Technescan DTPA

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 DTPA must not be used after the expiry date which is stated on the label on the vial after EXP. The expiry date refers to the last day of the month. Technescan DTPA must not be used if there are visible signs of deterioration.

6. Contents of the pack and other information

What TechneScan DTPA contains

- The active substance is: pentetic acid.
- Each vial contains 20.8 mg of pentetic acid.
- The other ingredients are: gentisic acid, stannous chloride dihydrate, calcium chloride dihydrate, sodium hydroxide, hydrochloric acid.

What TechneScan DTPA looks like and contents of the pack

Technescan DTPA is a grey-white to slightly yellow freeze-dried powder for Solution for Injection. It is packaged in 10 mL glass vials closed with a bromobutyl rubber cap and sealed with an aluminium cap.

Technescan DTPA is supplied in one pack containing 5 vials.

Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.

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