

Technescan HDP

Kit for radiopharmaceutical preparation.

sodium oxidronate

Read all of this leaflet carefully before you will be administered 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 HDP is and what it is used for
2. What you need to know before Technescan HDP is used
3. How Technescan HDP is used
4. Possible side effects
5. How Technescan HDP is stored
6. Contents of the pack and other information

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

This medicine is a radiopharmaceutical product for diagnostic use only.

Technescan HDP is used through a scan to examine the:

- **bones**

The use of Technescan HDP 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) oxidronate. When administered into the body it collects in certain organs such as the bones.

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 body. This gives the doctor valuable information about the structure and function of a specific part of the body.

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

Technescan HDP must not be used

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

Warnings and precautions

Take special care with Technescan HDP

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

Before Technescan HDP 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 HDP:

- **medicines to treat reduced bone density** with active substance names ending with "dronate"
- **vincristine, cyclophosphamide, doxorubicin, methotrexate:** cytostatics to treat cancer
- **immunosuppressive medicinal products (e.g. cortisone):** agents that inhibit or prevent activity of the immune system
- **gentamicin, amphotericin:** antibiotics
- **iron based medicines**
- **aluminium based stomach acid binding medicines**

Pregnancy, breast-feeding and fertility

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

Important information about some of the ingredients of Technescan HDP

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How Technescan HDP is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Technescan HDP 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 HDP 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 300 to 740 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 HDP and conduct of the procedure

Technescan HDP is administered by injection.

One injection is usually sufficient to conduct the test that your doctor needs. Dependent upon the information required, scans are made immediately or no sooner than 2 hours after the injection.

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 HDP, you should:

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

If you have been administered more Technescan HDP than you should

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

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 HDP, please ask the Nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, Technescan HDP 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:

frequency unknown, from the data available

- serious allergic reactions may occur with symptoms such as:
 - life-threatening allergic shock reaction, loss of consciousness
 - heart and respiratory arrest, breathing difficulties
 - mostly painful severe swelling of deep skin layers, mainly in the face
 - increased heartbeat, high blood pressure
 - inflammation inside the nose or of the outermost layer of the eye

- skin inflammation, reddening, rash, itching, increased sweating
- swellings of different types caused by excess fluid
- taste disturbance, sensation disorder such as pricking, burning

Hospital staff will treat these allergic reactions immediately, if they occur.

- severe reactions caused by the nervous system with symptoms such as
 - fainting fit, circulatory collapse
 - dizziness, headache
 - increased or reduced heart beat, low blood pressure
 - shakiness, blurred vision, flushing
- vomiting, nausea
- diarrhoea
- stomach pain
- injection site reactions such as inflammation, pain, skin reddening, swelling
- chest pain
- chills

Reporting of side effects

If you get any side effects, talk to your Nuclear medicine doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How Technescan HDP 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 information is intended for the specialist only.

Technescan HDP will not be used after the expiry date stated on the label.

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

6. Contents of the pack and other information

What Technescan HDP contains

- The active substance is: sodium oxidronate
- The other ingredients are: stannous chloride dihydrate, gentisic acid, sodium chloride, hydrochloric acid and sodium hydroxide

What Technescan HDP looks like and contents of the pack

Technescan HDP is a grey-white lyophilized powder. It is packaged in 10 ml colourless glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap with a blue flip-cap.

Pack size

Technescan HDP is supplied in a carton box that contains 5 vials.

Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.

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The Netherlands

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