

Technescan HDP 3 mg

kit for radiopharmaceutical preparation

sodium oxidronate

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

This medicine is a radiopharmaceutical product for diagnostic use only.

Technescan HDP contains the active substance sodium oxidronate. It is used for the preparation of a radioactive solution for injection of technetium (^{99m}Tc) oxidronate.

Technescan HDP is used in adults and children to determine if there is any **bone abnormality**. When injected, this medicine temporarily collects in your bones. Because of its radioactivity, it can be detected outside the body using special cameras, and pictures, known as scans, can be taken. These scans show the distribution of radioactivity within your body and give valuable information about the **metabolism of your 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.

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

Technescan HDP must not be used

- if you are allergic to sodium oxidronate, to any of the other ingredients of this medicine (listed in section 6), or to any of the ingredients of the radiolabelled product technetium (^{99m}Tc) oxidronate.

Warnings and precautions

Take special care with Technescan HDP

- if you are **pregnant** or believe you may be pregnant.
- if you are breast-feeding.
- if you have a **kidney disease**.
- if you have a condition called **hypercalcemia** (high calcium level in your blood).

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 HDP 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, in particular because higher radiation exposure may be observed in growing bones.

Other medicines and Technescan HDP

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 HDP:

- **medicines containing iron** (used to treat anaemia)
- **medicines containing aluminium salts** (used to treat gastric problems)
- **medicines to treat reduced bone density** with active substance names ending with "dronate"
- **some medicines to treat cancer** (vincristine, cyclophosphamide, doxorubicin, methotrexate)
- **some immunosuppressive medicines** (cortisone)
- **some medicines to treat infections** (gentamicin, amphotericin, tetracycline).

Pregnancy, breast-feeding and fertility

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

Moreover, you may need to avoid close contact with your baby for a short period (1 hour after the injection).

Driving and using machines

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

Technescan HDP contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say 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 technetium (^{99m}Tc) oxidronate 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** (MBq: megabecquerel, 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, usually into a vein of 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. This will increase the quality of the scan.

Duration of the procedure

Depending on the information required, the scans can be taken immediately and/or later after the injection (up to 24 hrs).

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

After administration of Technescan HDP, you should:

- avoid intense physical exercises until satisfactory scans have been taken, in order to prevent accumulation of the radioactive substance in your muscles,
- avoid any close contact with young children and pregnant women during 1 hour after the injection,
- 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 HDP than you should

An overdose is unlikely 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 the appropriate treatment.

In particular, the nuclear medicine doctor may recommend that you drink plenty of water and urinate frequently to remove the traces of radioactivity from your body.

If 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, 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** may occur with various symptoms such as:
 - life-threatening allergic shock, loss of consciousness
 - heart and respiratory arrest, breathing difficulties
 - mostly painful severe swelling of deep skin layers, mainly in the face, tongue and throat, swellings of different types caused by excess fluid
 - increased heart beat, high blood pressure
 - inflammation inside the nose or of the outermost layer of the eye
 - skin inflammation, reddening, rash, itching, increased sweating
 - taste disturbance,
 - sensation disorder such as pricking, burning

Contact a doctor immediately in case of allergic reactions.

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

- **Circulatory reactions** with symptoms such as:
 - fainting, circulatory collapse
 - dizziness, headache
 - increased or reduced heart beat, low blood pressure
 - shakiness, blurred vision, flushing
- **Gastro-intestinal reactions** with symptoms such as:
 - vomiting, nausea
 - diarrhoea
 - abdominal pain
- **Musculoskeletal reactions** with symptoms such as joint pain
- **Reactions at the injection site**, with symptoms such as skin infection, inflammation, pain, skin reddening, irritation of the skin and swelling
- **General reactions** with symptoms such as chest pain and chills

Onset of these reactions can be delayed 4 to 24 hours after injection.

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, Website: www.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 following information is intended for the specialist only.
Technescan HDP must not be used after the expiry date which is stated on the label after "EXP".
Technescan HDP must not be used if there are visible signs of deterioration.

6. Contents of the pack and other information

What Technescan HDP contains

- The active substance is sodium oxidronate (or sodium hydroxymethylene diphosphonate, HDP).

- The other ingredients are gentisic acid, hydrochloric acid, sodium chloride, sodium hydroxide, stannous chloride dihydrate.

What Technescan HDP looks like and contents of the pack

Technescan HDP is an off-white to slightly yellow lyophilized powder. It is a kit for radiopharmaceutical preparation intended to be used by healthcare professionals only.

Technescan HDP is packaged in a 10 ml colourless glass vial closed with a rubber stopper and sealed with an aluminium cap.

It is supplied in one pack that contains 5 vials.

Marketing Authorisation Holder and Manufacturer

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