

PACKAGELEAFLET

Package leaflet: Information for the user

Drytec 2.5-100 GBq radionuclide generator (called Drytec in this leaflet)

Sodium [^{99m}Tc]pertechnetate

Read all of this leaflet carefully before you are given Drytec 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 Drytec is and what it is used for
2. Before you are given Drytec
3. How Drytec is given
4. Possible side effects
5. How to store Drytec
6. Contents of the pack and other information

1. What Drytec is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Drytec is used to help identify illness.

Drytec is a ‘radionuclide generator’. It is used to make a liquid which is a ‘radiopharmaceutical medicine’. This liquid is given before a scan and helps a special camera see inside a part of your body.

- It contains an active ingredient called ‘sodium pertechnetate’.
- Once the liquid is injected it can be seen from outside your body by a special camera used in the scan.
- The scan can help your nuclear medicine doctor to see how well certain parts of your body are working such as the thyroid gland, saliva glands, brain, tear ducts and heart.
- Some other people are given this medicine to see how well fluids, such as the blood, are circulating within the body.
- It can be used to find bleeding in the gut.
- It can also be used to find a small pouch that some people have in the wall of their gut (‘Meckel’s diverticulum’).

Your nuclear medicine doctor or nurse will explain which part of your body will be scanned.

The use of Drytec does involve exposure to radioactivity. Your nuclear medicine doctor will have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. Before you are given Drytec

You should not be given Drytec if:

- if you are allergic (hypersensitive to Sodium [^{99m}Tc]pertechnetate or any of the other ingredients of this medicine (listed in section 6).

Do not have Drytec if the above applies to you. If you are not sure talk to your nuclear medicine doctor or nurse.

Warnings and precautions

Talk to your nuclear medicine doctor before having Drytec.

Take special care:

- If you are pregnant or believe you may be pregnant
- If you are breast-feeding
- If you are on a low sodium diet.

Before administration of Drytec you should:

- Drink lots of water
- If the scan is being used to find a small pouch that some people have in the wall of their gut ('Meckel's diverticulum') you should keep an empty stomach for around 3-4 hours before administration

Children and adolescents

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

Other medicines and Drytec

Please tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes medicines obtained without a prescription. This includes herbal medicines. This is because some medicines can affect the way Drytec works.

Before you have Drytec tell your nuclear medicine doctor or nurse if you are taking any of the types of medicine below. This is because they may affect the results of your scan.

For a **brain scan**:

- Methotrexate (used for lots of different illnesses, such as rheumatoid arthritis and some types of cancers).

For an **abdominal scan**:

- Atropine (used for heart, muscle or eye problems).
- Isoprenaline (used for heart problems).
- Painkillers.

If you are not sure if any of the above apply to you, talk to your nuclear medicine doctor or nurse before having Drytec.

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 Drytec 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 this product during pregnancy if a benefit is expected which would outweigh the risks.

Do not breast-feed if you are given Drytec. This is because small amounts of 'radioactivity' may pass into the mother's milk.

If you are breast-feeding

Your nuclear medicine doctor may wait until you have finished breastfeeding before giving you Drytec. If it is not possible to wait your nuclear medicine doctor will ask you to:

- stop breast-feeding, and
- use formula feed for your child, and

- express (remove) breast milk and throw away the milk.

Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines

Ask your nuclear medicine doctor if you can drive or use machines after you have been given Drytec.

Important information about Drytec

When Drytec is used you are exposed to radioactivity.

- Your nuclear medicine doctor will always consider the possible risks and benefits before you are given the medicine.

Ask your nuclear medicine doctor if you have any questions.

Drytec contains sodium chloride and water for injections.

3. How Drytec is given

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Drytec 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 Drytec 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 2 to 925 MBq (megabecquerel, the unit to express radioactivity).

- Drytec will always be used in a hospital or clinic.
- You may be asked to take a medicine to stop radioactivity building up in your thyroid gland.
- They will tell you anything you need to know for its safe use.

Your nuclear medicine doctor will decide the dose that is best for you.

Use in children and adolescents

In children and adolescents, the quantity to be administered will be adapted to the child's weight. Children and adolescents may be asked to take a medicine to stop radioactivity building up in your thyroid gland.

Administration of Drytec and conduct of the procedure

Drytec is administered intravenously.

One injection is sufficient to conduct the test that your nuclear medicine doctor needs.

For a scan of the tear ducts you will be given drops into the eye.

Duration of the procedure

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

After administration Drytec, you should:

- try to go to the toilet as often as possible

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 Drytec than you should

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

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

4. Possible side effects

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

Like all medicines, Drytec can cause side effects, although not everybody gets them. These can include:

- dizziness
- head-ache
- blurred vision
- feeling sick & vomiting
- diarrah
- swelling, pain or redness at the injection site

Allergic reactions

If you have an allergic reaction when you are in hospital or a clinic having the scan, tell the nuclear medicine doctor or nurse straight away. The signs may include:

- skin rash or itching or flushing
- swelling of the face
- difficulty breathing.

In more serious cases reactions may include:

- a change in your heart rate (fast, slow or irregular)
- coma (unconsciousness).

If any of the side effects above happen after you leave the hospital or clinic, you should go or be taken straight to the casualty department of your nearest hospital.

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 the national reporting system:

Ireland:

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

5. How to store Drytec

Drytec is kept out of the reach and sight of children.

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.

Keep this medicine out of the sight and reach of children.

The following information is intended for the specialist only.

6. Contents of the pack and other information

What Drytec contains

- The active substance is sodium [^{99m}Tc]pertechnetate
- The other ingredients are sodium chloride and water for injections.

What Drytec looks like and contents of the pack

Drytec is a radionuclide generator. The internal generator components are contained within a plastic casing fitted with a carrying handle.

Marketing Authorisation Holder and Manufacturer

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De Rondon 8

5612 AP

Eindhoven

The Netherlands

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Marketing Authorisations

Ireland: PA 22734/002/001

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