Package leaflet: Information for the patient

Tektrotyd 20 micrograms, kit for radiopharmaceutical preparation

HYNIC-[D-Phe^{1},Tyr^{3}-Octreotide] trifluoroacetate

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.

What is in this leaflet:

1. What Tektrotyd is and what it is used for

This medicine is a radiopharmaceutical product used to help identify (diagnose) some medical problems.

In particular, it is used to make images of specific cells in the stomach, bowel and pancreas such as:
- **abnormal tissue or**
- **tumours**

Tektrotyd bound to radioactive isotope attaches to abnormal or tumour cells that have receptors for it (somatostatin receptors). Later, radiation-measuring device (gamma-camera) detects the radiation, and makes pictures showing where the abnormal/tumour cells are in the body.

The use of Tektrotyd 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 Tektrotyd is used

Tektrotyd must not be used
- if you are allergic to the active substance of Tektrotyd, or to any of the excipients of this medicine (listed in section 6) or to sodium pertechnetate (^{99m}Tc) solution for injection
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding. Please see the section “Pregnancy and breast-feeding” below.

Warnings and precautions

Take special care with Tektrotyd if you are diagnosed with kidney failure.

If any of the above information applies to you, please tell your nuclear medicine doctor.

Before administration of Tektrotyd

In order to obtain the best image quality adequate patient preparation before administration of radiopharmaceutical is required.

Unless your doctor tells you otherwise, a liquid diet is recommended two days before the examination.

Your doctor may recommend the administration of laxatives on the day preceding the examination.

On the day of the examination fasting should continue until the recording of the first pictures is completed. You may be asked to drink plenty of water and to be well hydrated before the start of examination in order to urinate as often as possible during the first hours after the study

The method of patient preparation may be different, dependent on the examination protocol applied and the localization of imaged lesions. Your doctor will determine the preparation.

Children and adolescents

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

Other medicines and Tektrotyd

A number of drugs can adversely affect the outcome of the planned investigation. It is therefore recommended to discuss with the referring physician, which medication should be discontinued before the investigation and when the medicinal products should be taken again.

Tell also your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, since they may interfere with the interpretation of the images.

For example you should tell your doctor if you are using so called “somatostatin analogues” for the treatment of certain tumours.

Pregnancy and breast-feeding

You must inform the nuclear medicine doctor before the administration of Tektrotyd 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.

<u>If you are pregnant</u>

The use of Tektrotyd must not be given to pregnant women due to the potential radiation risk incurred by the mother and the foetus.

<u>If you are breast-feeding</u>

Tell your doctor if you are breast-feeding as he/she may delay treatment until breast-feeding is finished. He/she may also ask you to interrupt breast-feeding and discard expressed 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

There are no studies on the effects of Tektrotyd on the ability to drive and use machines.

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

Tektrotyd contains sodium

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

3. How Tektrotyd is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Tektrotyd 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 Tektrotyd 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 370 MBq to 740 MBq (megabecquerel, the unit used to express radioactivity).

Administration of Tektrotyd and conduct of the procedure
After radiolabelling the drug is administered as a single intravenous injection. This product is not intended for regular or continuous administration.
After injection you will be offered a drink and asked to urinate immediately preceding the test.

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

After administration of Tektrotyd, you should
urinate frequently in order to eliminate the product from your body.

Close contact with infants and pregnant women should be avoided during the first 24 hours after you have been given Tektrotyd.

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 further questions.

If you have been given more Tektrotyd than you should
An overdose is unlikely, because you will only receive a single dose of Tektrotyd precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment increasing the elimination of the radionuclide from the body, e.g. by administration of liquids and frequent bladder voiding.

Should you have any further question on the use of Tektrotyd, 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.

Very rarely (affects less than 1 patient out if 10 000), immediately after administration of Tektrotyd there may be transient headache or epigastric pain.

This radiopharmaceutical will deliver low amounts of ionizing radiation. It is very rare that this is associated with 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 the national reporting system.
Adverse reactions may be reported to Marketing Authorisation Holder.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How Tektrotyd 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.
Tektrotyd must not be used after the expiry date which is stated on the labels.

6. Contents of the pack and other information

What Tektrotyd contains
Vials I and II contain components for the radiopharmaceutical preparation of ^{99m}Tc-Tektrotyd.

Vial I:
The active substance is
HYNIC-[D-Phe^{1},Tyr^{3}-Octreotide] trifluoroacetate

The excipients are:
stannous chloride dihydrate, N-[tris(hydroxymethyl)methyl]glycine (tricine), mannitol, sodium hydroxide or hydrochloric acid for pH adjustment, nitrogen

Vial II:
The excipients are:
ethylenediamine-N,N'-diacetic acid (EDDA), disodium phosphate dodecahydrate, sodium hydroxide, sodium hydroxide or hydrochloric acid for pH adjustment, nitrogen

What Tektrotyd looks like and contents of the pack

The package contains two different glass vials of 10 ml in a cardboard box.
Each vial contains a white or nearly white lyophilisate for preparation of a solution for injection.
Pack size: 2 vials for shared application

Marketing Authorisation Holder and Manufacturer
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The following information is intended for medical or healthcare professionals only:

The complete SmPC of Tektrotyd 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.