Package leaflet: Information for the patient
TEKTROTYD 16 μg
Kit for radiopharmaceutical preparation
Active substances: HYNIC-[D-Phe1, Tyr3-octreotide] TFA salt
EDDA (Ethylene diamine-N,N'-diacetic acid)

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
2. What you need to know before TEKTROTYD is used
3. How TEKTROTYD is used
4. Possible side effects
5. How TEKTROTYD is stored
6. Contents of the pack and other information

1. What TEKTROTYD is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only. It is used to make images of specific cells in the stomach, bowel and pancreas such as:
- abnormal tissue or
- tumours

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 HYNIC-[D-Phe1, Tyr3-octreotide] TFA salt, to EDDA (Ethylene diamine-N,N'-diacetic acid) or to any of the excipients of this medicine (listed in section 6) or to sodium pertechnetate ($^{99m}$Tc) solution for injection.

Warnings and precautions
Take special care with TEKTROTYD
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding
- 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 light 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.

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 intake 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.

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.

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.

If you are breast-feeding
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.

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 TEKTRONYD than you should
An overdose is unlikely, because you will only receive a single dose of
TEKTRONYD precisely controlled by the nuclear medicine doctor su-
watching the procedure. However, in the case of an overdose, you will
receive the appropriate treatment increasing the elimination of the ra-
dionuclide from the body, e.g. by administration of liquids and frequent
bladder voiding.

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

During the evaluation of side effects the following frequency data are
taken as a basis:

- very common: more than 1 patient out of 10
- common: 1 to 10 patient out of 100
- uncommon: 1 to 10 patient out of 1000
- rare: 1 to 10 patient out of 10000
- very rare: Less than 1 patient out of 10000
- not known: frequency cannot be estimated from available data

Very rarely, immediately after administration of TEKTRONYD 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 doctor, pharmacist or nurse. This
includes any possible side effects not listed in this leaflet. You can also
report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard. By reporting side effects you can help
provide more information on the safety of this medicine.

5. How TEKTRONYD 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.

TEKTRONYD must not be used after the expiry date which is stated on
the labels.

6. Contents of the pack and other information
What TEKTRONYD contains
Vials 1 and 2 contain components for the radiopharmaceutical prepa-
ration of technetium (99m) tektryod.

Vial 1:
The active substance is HYNIC-[D-Phe1, Tyr3-octreotide] TFA salt

The excipients are
- stannous chloride dihydrate,
- tricine (N-tris(hydroxymethyl)methyl]glycine),
- mannitol,
- nitrogen

Vial 2:
The active substance is EDDA (ethylenediamine-N,N'-diacetic acid).

The excipients are
- disodium hydrogen phosphate dodecahydrate, sodium hydroxide, ni-
-rogen

What TEKTRONYD 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

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This leaflet was last revised in June 2019.

The following information is intended for medical or healthcare profes-
sionals only:

The complete SmPC of TEKTRONYD 16 μg Kit for radiopharmaceutical
preparation is provided as a separate document in the product pack-
age, 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.