^{99m}Tc-Tektrotyd,
Kit for radiopharmaceutical preparation, 16 µg
Technetium ^{99m}Tc-HYNIC-Tyr^3-Octreotide

Pharmaceutical form

Kit for radiopharmaceutical preparation.

Therapeutic indications

^{99m}Tc-Tektrotyd, kit for radiopharmaceutical preparation is for diagnostic use only. ^{99m}Tc-Tektrotyd is a radiopharmaceutical indicated for diagnostics of pathological lesions in which somatostatin receptors are overexpressed (particularly subtype 2 and, to a lesser extent, subtypes 3 and 5) and which may be imaged by the labelled ligand.

In particular, these are:
- Gastro-entero-pancreatic neuroendocrine tumours (GEP-NET);
- pituitary adenomas;
- tumours originating in a sympathetic system; pheochromocytoma, paraganglioma, neuroblastoma, ganglioneurinoma etc.;
- medullary thyroid carcinoma;
- the preparation may be potentially useful in the case of other tumours expressing somatostatin receptors of various intensity. Other tumours which may overexpress somatostatin receptors: breast cancer, melanoma, lymphomas, prostate cancer, NSCLC, sarcoma, renal cell carcinoma, differentiated thyroid carcinoma, astrocytoma according to WHO I-IV (including glioblastoma multiforme G-M), meningiomas, ovarian cancer.

Posology and method of administration

The medicinal product is for hospital use or in designated nuclear medicine facilities only, by persons experienced in the radiopharmaceuticals application.

^{99m}Tc-Tektrotyd is administered intravenously in a single dose after labelling of the kit using a sterile, oxidant-free sodium pertechnetate (^{99m}Tc) solution for injection (eluate of ^{99}Mo/^{99m}Tc radionuclide generator) in accordance with the instructions for preparation of radiopharmaceutical. Technetium-99m in 1 ml of eluate of sodium pertechnetate- ^{99m}Tc solution for injection with activity of 740 MBq - 1200 MBq (maximally 2200 MBq) may be used for labelling of one kit. This activity is sufficient for examinations of 1 – 2 adults. Radioactivity of administered dose should be always adjusted with respect to its diagnostic usefulness. The solution of ^{99m}Tc-Tektrotyd may be additionally diluted for more convenient administration. Acquisition should be carried out between 2 – 4 hours after intravenous administration of the preparation. The examination may be complemented by acquisition after 10 minutes, 1 hour and 24 hours after administration of the preparation. It is recommended to carry out the examinations using Whole Body technique and SPECT of selected body areas.

Preparation of the patient for examination

Unless there are indications for other method of the patient preparation, the patient is recommended to stay on light diet one day before examination. On the day of examination, the patient should fast until the end of the first acquisition. If there is a need for examination after 24 hours, it is recommended that a mild laxative be given to the patient starting the evening before. Method of patient preparation may depend on the applied examination protocol and the localization of imaged lesions. However, optimal imaging of abdominal cavity is obtained after the application of liquid diet 2 days before the examination and after administration of laxatives on the day before the examination.

Dosage for adults

The recommended radioactivity dosage for single examination of adult is approximately 370 to 925 MBq.

Dosage for elderly (above 65 years)

Experience from literature data indicates that no dose adjustment is required.

Children

^{99m}Tc-Tektrotyd is not recommended for use in patients under 18 years of age; there are no data for this age group.

Patients with renal impairment

No dosage adjustment is required.

Repeated administration

^{99m}Tc-Tektrotyd is intended for a single intravenous use only. If there is a need for repeated administration, clinical indication and potential adverse events should be considered.

Contraindications

Hypersensitivity to HYNIC-[D-Phe^1, Tyr^3-Octreotide] · TFA or to any of the excipients or sodium pertechnetate (^{99m}Tc) solution for injection.

Pregnancy

The preparation must not be administrated to pregnant women.

When it is necessary to administer radiopharmaceuticals to women of childbearing potential information should always be sought about pregnancy. Pregnancy should be excluded in any women who has had menstrual cycle disturbances. Any women who has missed a period should be assumed to be pregnant until proven otherwise.

Special warnings and precautions for use

The content of the kit vials is intended for preparation of radiopharmaceutical ^{99m}Tc-Tektrotyd and may be administered to a patient only after completion of labelling procedure. The preparation should not be administered before labelling.
Particular attention should be given to patients with renal insufficiency – when renal excretion is prolonged, the patient is exposed to higher dose of radioactivity.

Patients with liver failure should be also provided with particular care.
The radiopharmaceutical should be received, stored and administered to patients only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to appropriate regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals intended for administration to patients should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements.

Safety precautions for careful handling this radiopharmaceutical should be observed to ensure protection of the staff and patients against unnecessary exposure to ionising radiation. There are no data on safety and efficacy of the use in children under 18 years of age.

An adequate hydration of a patient and frequent voiding are necessary to minimize radiation dose to the bladder.
The exposure to radiation can be increased in patients with renal insufficiency. This should be considered in the calculation of the dose to be administered.

Repeated administration of the preparation
If there is a need for repeated examination, clinical indications and potential adverse events should be considered.

Qualitative and quantitative composition

HYNIC-[D-Phe^1, Tyr^3-Octreotide] · TFA, 16 µg

List of excipients

Tricine (N-[Tris(hydroxymethyl)methyl]glycine, tin (II) chloride dihydrate, mannitol, EDDA (ethylenediamine-N,N'-diacetic acid), disodium hydrogen phosphate dodecahydrate, sodium hydroxide, nitrogen.

Shelf life

Shelf life of the kit: 1 year
Labelled product must be used within 6 hours after preparation. Data on radiochemical purity and stability of the preparation have been demonstrated for 6 hours at temperature below 25°C.

Special precaution for storage

Store the kit in a refrigerator at 2°C - 8°C.
Expiry date is indicated on the package.
After labelling, store the medicinal product for no more than 6 hours at temperature below 25°C using appropriate radiation shielding. Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

Nature and content of the container

The kit package contains two glass vials (Vial I and Vial II) of 10 ml volume, closed with a rubber stopper and an aluminium crimp cap. The vials are supplied in cardboard boxes. Vials I and II contain components for preparation of a radiopharmaceutical ^{99m}Tc-Tektrotyd.

Vial I: HYNIC-[D-Phe^1, Tyr^3-Octreotide] ·TFA, tin(II)chloride dihydrate, tricine (N-[Tris(hydroxyme-thyl)methyl]glycine), mannitol, nitrogen – gas filling the vial.

Vial II: EDDA (ethylenediamine-N,N'-diacetic acid), disodium hydrogen phosphate dodecahydrate, sodium hydroxide, nitrogen – gas filling the vial.

Classification for supply:

Medicinal product subject to medical prescription

Marketing Authorisation No. 11664

Quality assurance

Certified for conformity with ISO 9001: 2008, International Control System and Good Manufacturing Practice.

Marketing authorisation holder and manufacturer:

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