LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

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

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Summary Public Assessment Report

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

Kit for radiopharmaceutical preparation; 20 micrograms

This is a summary of the public assessment report (PAR) for Tektrotyd. It explains how Tektrotyd was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Tektrotyd.

For practical information about using Tektrotyd, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tektrotyd and what is it used for?

Tektrotyd is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Tektrotyd is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Tektrotyd 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

How does Tektrotyd work?

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.

How is Tektrotyd used?

The pharmaceutical form of Tektrotyd is kit for radiopharmaceutical preparation. After radiolabelling the drug is administered as a single intravenous injection.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Tektrotyd have been shown in studies?

As HYNIC-[D-Phe^{1},Tyr^{3}-Octreotide] trifluoroacetate is a well-known substance, and its use in the treatment of identifying medical problems (such as abnormal tissue or tumours) is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of HYNIC-[D-Phe^{1},Tyr^{3}-Octreotide] trifluoroacetate in the treatment of identifying medical problems (such as abnormal tissue or tumours).

What are the possible side effects of Tektrotyd?

For the full list of all side effects reported with Tektrotyd, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why is Tektrotyd approved?

The use of Tektrotyd in the treatment of identifying medical problems (such as abnormal tissue or tumours) is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Tektrotyd's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Tektrotyd?

A risk management plan has been developed to ensure that Tektrotyd is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tektrotyd, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Tektrotyd

The marketing authorisation for Tektrotyd was granted on 2016-11-29 in Sweden.

The full PAR for Tektrotyd can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Tektrotyd, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2017-03.