SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Techida 30 mg powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One injection vial contains 51.3 mg hypophosphate with the next composition:

- Diethyl-amino-oxalic acid 20.0 mg
- Sodium hydroxide
- Sodiumchloride 0.2 mg
- Sodium pertechnetate

Excipients:
The product contains 7.86 mg sodium as excipient.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation.
Powder for solution for injection.
The medicinal product must be reconstituted with sodium pertechnetate (99mTc) for injection.
Sterile, pyrogen-free, white powder (hypophosphate).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Indication area:
- Imaging of biliary tree (including gallbladder).
  - Imaging of liver transplants.
  - Isotope diagnostics of hepatobiliar system.

4.2 Possibility and mode of administration

Method of examination:

The number of patients to be examined from the labeled composition is determined after measuring the radioactivity of the images. Generated curve by using the data of the images obtained in 10–15 minutes after the start imaging and intravenous injection.

Method of administration:

For paediatric examination use Webster’s equation (given below) to determine the dose of 99mTc-Techida. According to the table in Chapter 11, the most endangered organ is the bladder, the exposure of the maximum permissible dose in the bladder should be considered.

The following three factors predominantly govern the excretion of 99mTc-Techida by the liver: the liver function, the intensity of blood flow through the liver, and the hepatocyte function.

4.3 Contraindications

- Pregnancy and lactation (See section 4.6) except if the necessity and importance of obtaining the diagnostic information outweighs the risk associated with the radiation exposure.
- The medicinal product must be reconstituted with sodium pertechnetate (99mTc) for injection.
- The patient does not provide an oral or written consent of being examined using radioisotopes.

4.4 Special warnings and precaution for use

The demand for an isotope diagnostic test should be well indicated, based on the previous diagnosis of the patient and the possible lowest activity should be used. The radiopharmaceuticals (99mTc) Techida is not radioactive imaging agent. Except, storage, use and transfer and disposal of the radioactive medicinal products are subject to the regulations and appropriate licences of the competent authorities. Radiopharmaceutical medicinal products should be received, used and administered only by authorised person in designated area and should meet the criteria both of radiation safety and pharmaceutical quality requirements. Appropriate lead shielding should be used during the preparation of the 99mTc-Techida. To protect the patient and the staff from the risk of radiation, as it is possible.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions have been reported.

4.6 Fertility, pregnancy and lactation

Diethyl-amino-oxalic acid (DHAA) associated with the radiation exposure. When it is necessary to administer radiopharmaceutical medicinal products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be presumed pregnant until proven otherwise. Alternatively, if the pregnancy investigation could be reasonably delayed until the mother has ceased breast feeding.

Treatment of women of childbearing potential is recommended in the first 10 days after menstruation.

4.7 Effects on ability to drive and use machines

Techida has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse event and reactions have not been reported ever since the authorisation of the product (1985) nor registered in the literature. Considering the number of the investigations carried out so far, no adverse reactions are expected (frequency lower than 1/10 000).

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. However these effects are hardly expected regarding the exposure in normal clinical practice.

According to the table in Chapter 11, the most endangered organ is the bladder, the dose absorbed in the bladder for standard 120 Mbq administered activity, the total dose is 0.12 mSv, e.g., the effective dose reduces below 20 mSv.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Diagnostic radiopharmaceuticals, ATC code: V09DA02

After intravenous administration 99mTc-Techida binds to plasma proteins and is excreted by the liver. The 99mTc-Techida is an isotope from +7 oxidation state to +4 oxidation state, in which technetium readily associates with hepatocytes. Technetium-99mTc-Techida is therefore suitable as a radiopharmaceutical agent for the liver and its excretion is via the urinary system, which is similar to that of bilirubin. Uptake of the 99mTc-Techida by the hepatocytes is a function of the blood flow to the liver. It is necessary to ensure that the patient has eaten rice or bread 1–2 hours before the imaging.

5.2 Pharmacokinetic properties

99mTc-Techida rapidly eliminates from the bloodstream, the half-life after administration less than 1% of the substance is present. It appears in the liver about 1 minute after administration and reaches its highest activity after 10–15 minutes. Hepatic excretion normally has a half-life of 20–25 minutes. The half-life highly depends on the plasma albumin concentration, intensity of blood circulation and hepatocyte function. 15 minutes after administration 5% destruction of 99mTc-Techida images and after 30 minutes the gallbladder becomes visible. Highest activity in the gallbladder is reached after 30–40 minutes. 40–45 minutes after administration the destruction is well visible on the images.

5.3 Preclinical safety data

An intravenous acute toxicity study of mice showed no clinical symptoms up to 9 mg/kg bodyweight. There is no data of 0.8 % of the substan, substance is administered to one patient by mistake, it represents 0.43 mg/kg of bodyweight level (calculated on 70 kg average bodyweight). This is equivalent to 4.8 % of the no observed effect level. Thus, no toxic effects are expected in case of overdose.

5.4 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER

Institute of Isotopes Co. Ltd.
Address: 1121 Budapest, Konkoly Thege Miklós str. 29–33.
1133 Budapest, P.P. 8.5
Telephone: 36 1 439 2257, 36 1 439 9081, 36 1 439 9247, 32 2575
Email: iot@iot匈牙利, radiopharm@iot匈牙利

MARKETING AUTHORISATION NUMBER(S)
OYTL-02/001

DATE OF REGISTRATION
DATE OF REVISION OF THE TEXT
4.3 Whole body

The 99mTc-Techida is a generator of β-decay.
12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Preparation of 99mTc-Techida

Remove the protective foil and lift up the upper part of the paper box to access the vials. Techida vial can only be administered to patient after labelling with sodium pertechnetate (99mTc) solution in injection (Ph. Eur.). Only the labelled 99mTc-Techida injection can be administered.

Labelling procedure:
All procedures have to be carried out aseptically conditions.
Place the vial containing the freeze-dried powder in a small lead container with a wall thickness of 3 mm and inject 0.8 - 3 mm volume of sterile sodium pertechnetate (minimal volume: 2 ml, max. volume: 5 ml) into the vial through the rubber stopper with a sterile syringe.
Shake well and allow to stand at room temperature for 15 minutes. The 99mTc-Techida injection can be used for intravenous administration. pH of the medicinal product is in the range of pH = 5 - 7.

Quality control
Radiocompounds purity of the injection Ph. Eur. 2.2.27

Determination of radiocompounds purity of the injection (according to Ph. Eur. 2.2.27)

Preparation of injection: place one vial of Techida into a lead container. Inject the 99mTc eluate of having activity of 800 to 1600 MBq in no more than 5 ml volume into the vial without removing its cap (through rubber stopper). Shake thoroughly allow 15 minutes for the reaction to take place. Label one vial and develop three replicate chromatograms in a test.

Development of chromatograms: Examine by thin-layer chromatography using 254 nanometers visible light as the coating substance on a glass plate (Merk, 105859). Heat the plate at 110°C for 10 minutes cool down before use. Apply to the plate 5 µl of the injection to be examined without drying. Develop immediately over a path of 15 cm using a 9 g/l solution of sodium chloride (saline). After that allow the plate to dry. Determine the distribution of radioactivity by gamma scanner.

Specifications:
Expected Rf values are:
Colloidial technetium 0.0-0.2 (start)
Labelled complex 0.5
Other ingredients are: starch acetanilid, ascorbic acid, sodium chloride.

The radiochemical purity (the relative amount of labelled complex) is not less than 96%.

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Techida 30 mg powder for solution for injection

99mTc-diolylacetatimidodimercaptosuccinic acid

Read all of this leaflet carefully before you take 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 doctor or health care professional.
• If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?
1. What Techida 30 mg powder for solution injection is and what it is used for?
2. How to store Techida 30 mg powder for solution injection?
3. Contents of the pack and other information.

1. What Techida 30 mg powder for solution injection is and what it is used for?
This medicine is for diagnostic use only.

99mTc-Techida injection prepared from Techida kit is a colourless, sterile solution that contains radioactive isotope and is to be used as a radiopharmaceutical. Use of Techida is permitted only in departments of nuclear medicine.

99mTc-Techida injection is administered intravenously. After intravenous administration, 99mTc-Techida injection is transported to the liver via the blood circulation. As the medicine contains gamma-emitting radioactive isotope, it can be detected from outside the body using gamma cameras. The gamma cameras record the radiation emitted by the distribution of the radioactive isotope in your body and the organs. The pictures taken by this camera show the distribution of the radioactive isotope in the liver, gallbladder and duodenum helping this way to choose the best treatment.

2. What you need to know before you Techida 30 mg powder for solution for injection is used for your examination
Do not use Techida 30 mg powder for solution for injection:
• you are allergic to pertechnetate (99mTc) solution for injection or any of the other ingredients of Techida (section 6).
• if you are under 18 years of age, except if your doctor decides otherwise.
• if you are under 18 years of age, except if your doctor decides otherwise.

Warnings and precautions
Tell your doctor if you are taking any other medicines or herbal products.

Techida 30 mg powder for solution for injection contains:
• The active substance is 30 mg diolylacetimidodimercaptosuccinic acid.
• Other ingredients are: sodium chloride, disodium ethylene diamine tetra acetic acid, sodium acetate, benzoic acid.

3. How to use Techida 30 mg powder for solution for injection?
99mTc-Techida injection is prepared by mixing the content Techida kit and radioactive pertechnetate at the site of the use (hospitals, clinics). The injection is administered intravenously.

Package leaflet: Information for the patient
Pharmacy and Nutrition
Box: 456
H-1172 Budapest
Website: www.ogyei.gov.hu

This leaflet was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy in May 2017.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder Hungary
National Institute of