



SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Techida 30 mg powder for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition of Techida powder for injection

<i>Component Active substance</i>	<i>Quantity per vial</i>	<i>Function</i>
N-(2,6-diethylacetamidyl)-imino diacetic acid	30.0 mg	Organ-specific chelating agent of ^{99m} Tc radioisotope

Composition of ^{99m}Tc-Techida radioactive injection

<i>Component Active substance</i>	<i>Quantity per vial</i>	<i>Function</i>
^{99m} Tc-Techida	0.8–1.6 GBq	Organ-specific diagnostic information

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pharmaceutical form of Techida kit: powder for injection (lyophilisate)
Pharmaceutical form of ^{99m}Tc-Techida: injection

^{99m}Tc-Techida injection can be prepared in situ at the site of the use i.e. at isotope laboratories of clinics or hospitals by mixing Techida powder for injection (lyophilisate in the vial) and [^{99m}Tc]pertechnetate eluate. Sterile, pyrogen free solution of [^{99m}Tc]pertechnetate can be obtained by using ⁹⁹Mo/^{99m}Tc generator.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

INDICATION FIELD: ISOTOPE DIAGNOSTICS of hepatobiliary system

- Dynamic examination of the function of the hepatocytes
- Liver transplant evaluation
- Dynamic examination of flow disorders in the hepatobiliary system (blockage in the biliary duct, etc.)
- Examination of the acute cholecystitis
- Verification of focal nodular hyperplasia

4.2 Posology and method of administration

The recommended dose is 150 - 200 MBq of ^{99m}Tc-Techida for intravenous use.

For paediatric examination (see Chapter 4.3.) use Webster's equation to determine the activity to be administered:

$$A_{\text{child}} = [(N+1)A_{\text{adult}}] / (N+7)$$

where N: age of the child [year]

$$A_{\text{child}}, A_{\text{adult}}: \text{activity [MBq]}$$

Method of administration

^{99m}Tc-Techida obtained in one labelling reaction can be divided to 3 – 6 dose. Label content of one vial of Techida kit by using 0.8 – 1.6 GBq of activity.

^{99m}Tc-pertechnetate activity for labelling must be chosen so that individual patient dose should be 150– 200 MBq at the time of the investigation.

4.8 Undesirable effects

Adverse event and reactions have not been reported ever since the authorization of the product (1985) nor registered in the literature. Considering the number of the examinations carried out since, no adverse reactions are expected (frequency lower than 1/10000).

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 applied amount of activity.

According to the table in Chapter 11, the effective dose is far below 20 mSv.

4.9 Overdose

No case of overdose has been reported.

Administration of higher activities than prescribed is unnecessary and must be avoided in order to avoid the excess absorbed radiation dose of the patient and his/her environment.

In case of incidental overdose, the effectively administered activity of ^{99m}Tc must be determined (in MBq) and the actual absorbed radiation dose must be calculated by using the data of the dosimetric table of Chapter 11. Necessity and method of further treatment should be concluded based on these results. The table of Chapter 11 contains absorbed radiation dose data in µGy in case of intravenous administration of 1 MBq of ^{99m}Tc-Techida. Multiply these specific absorbed radiation dose data by the effectively administered activity (in MBq) to obtain the required absorbed radiation dose data in µGy.

Quantity of ^{99m}Tc-Techida administered to one patient is not less than 5 mg and not more than 10 mg if administration is complying with the recommendations. If the whole content of the vial containing the labelled substance is administered to one patient by mistake 30 mg of ^{99m}Tc-Techida is introduced in the body.

Acute toxicity studies on mice showed no clinical symptoms if less than 9 mg/kg of bodyweight is administered. If the whole content of the vial containing the labelled 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. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceutical, ATC code: V09DA02

After administered intravenously ^{99m}Tc-Techida binds to plasma proteins and is transported to the liver where hepatocytes uptake it by active transport in a anionic process which is similar to that of bilimbin.

Uptake of ^{99m}Tc-Techida by the hepatocytes highly depends on the liver function. High levels of serum bilirubin inhibit the excretion of ^{99m}Tc-Techida via the liver which brings about that the significant percentage of the activity is excreted via the kidneys. In this case, the bladder appears intensively on the images of the gamma camera test.

The following three factors predominantly govern the excretion of ^{99m}Tc-Techida by the liver:

- Plasma albumin concentration,
- Intensity of the blood flow through the liver,
- Hepatocyte function.

^{99m}Tc-Techida is excreted either in a non-metabolised form or bound to bile acids. The normal way of elimination is: liver – gallbladder – duodenum – intestines.

5.2 Pharmacokinetic properties

^{99m}Tc-Techida rapidly eliminates from the blood; one hour after administration less than 1 % of the substance is present. It appears in the liver one minutes 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 the bile duct appears on the images and after 30 minutes the gallbladder becomes

visible. Highest activity in the gallbladder is reached after 30 – 45 minutes. 40 – 45 minutes after administration duodenum is well visible on the images.

5.3 Preclinical safety data

Acute toxicity study of mice showed no clinical symptoms up to 9 mg/kg of bodyweight. Quantity of ^{99m}Tc-Techida, if administration is complying with the recommendations, is not less than 5 mg and not more than 10 mg which are equivalent to 0.8 and 1.6 % of the no observed effect level, respectively. Thus, there is no special hazard for humans and the use of the product is safe.

Further advantage of the product is that the activity of [^{99m}Tc]pertechnetate in the range of 0.8 –1.6 GBq does not affect the radiochemical purity of the preparation. Quantity of radiochemical impurities is always less than 10 %, therefore the kit is safe from the point of view of labelling.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<i>Component</i>	<i>Quantity per vial</i>	<i>Function</i>
<i>Excipients</i>		
Stannous chloride dihydrate	1.0 mg	Reducing agent of [^{99m} Tc]pertechnetate
Ascorbic acid	0.3 mg	Stabiliser
Sodium chloride	20.0 mg	Filler

6.2 Incompatibilities

Stannous chloride component of Techida kit is a reducing agent. It reduces free pertechnetate from +7 oxidation state to +4 oxidation state, in which technetium readily forms complex with Techida. It is important to keep away the content of the vials from moisture and oxidising agents, for example chemical oxidation agents or oxygen of the air. Alkaline media facilitate the oxidation of Sn(II) before the labelling reaction this is why the product is incompatible with bases. As a result of these incompatibilities it is recommended to remove the closure of the closed injection vials just before the labelling reaction. Perform the labelling by observing the instructions detailed in Chapter 12.

For preparation of ^{99m}Tc-Techida only ^{99m}Tc-pertechnetate- and physiological saline solution can be used (See chapter 12). The Techida kit is incompatible with other materials.

6.3 Shelf life

Shelf life of Techida kit (lyophilised, non-radioactive components in injection vials closed with rubber stopper and aluminium komicap) is 6 month from the date of the manufacture.

One paper box contains 6 of injection vials, which can be labelled at different times within the expiry time.

^{99m}Tc-labelled Techida must be used within 3 hours.

6.4 Special precautions for storage

Store in refrigerator (2 - 8°C.) in its original box..

Do not store ^{99m}Tc-Techida injection above 25°C. Comply with the regulations for radiation safety.

6.5 Nature and contents of container

The injection vials of Techida kit contain the sterile, pyrogen-free and freeze-dried components. The labelled 6 ml injection vials are closed with rubber stopper and tear-off aluminium komicap. One box contains six vials, one Summary Of Product Characteristic and Patient Information Leaflet and six labels with radioactive material sign. The box is wrapped in shrinking foil.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

Techida kit can only be administered to patient after labelling with ^{99m}Tc solution. Never administer Techida kit without performing the labelling.

7. MARKETING AUTHORISATION HOLDER

Institute Of Isotopes Co. Ltd.

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8. MARKETING AUTHORISATION NUMBER(S)

OGYI-T-9210/01

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 March 1985 / 17 December 2009

10. DATE OF REVISION OF THE TEXT

17 December 2009

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 17.12.2009.

11. DOSIMETRY

Individual patient dose is 150 – 200 MBq. Estimated absorbed dose values of 1 MBq of the injection for an average body weight of 70 kg are given in the table below.

Organ	Absorbed dose [μGy / MBq]
liver	20.5
choleoductus	246.0
kidneys	12.0
ovaries	16.7
whole body	4.3

Radiation physical properties

Physical half-life 6 hours

Energy and intensity of the emitted gamma photons 140 keV 100 %

Energy and intensity of the emitted beta particles – –

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Remove the protective foil and lift up the upper part of the paper box to access the vials.

Techida kit can only be administered to patient after labelling with ^{99m}Tc. Never administer Techida kit without performing the labelling.

^{99m}Tc-Techida injection contains radioactive isotope. For handling, shipping and storage of this product the rules and regulations referring to the radioactive materials should be observed.

Labelling procedure

Place the vial containing the freeze-dried powder in a small lead container with a wall thickness of 3 mm. Under aseptic circumstances inject 0.8 – 1.6 GBq 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 for 15 minutes. This solution can be used for intravenous administration. pH of the labelled solution is in the range of pH = 5 – 7.

Utilize the labelled solution in 3 hours. Over this period the percentage of radiochemical impurities should not be more than 10%.

Any unused product or waste material should be disposed of in accordance with local requirements.



PACKAGE LEAFLET: INFORMATION FOR THE USER

Techida 30 mg powder for injection

N-(2,6-diethyl-acetamidil)-imino diacetic acid

Read all of this leaflet carefully before this medicine is used for your examination.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Techida is and what it is used for
2. Before you use Techida
3. How to use Techida
4. Possible side effects
5. How to store Techida
6. Further information

1. WHAT TECHIDA IS AND WHAT IT IS USED FOR

This medicine is for diagnostic use only.

^{99m}Tc-Techida injection prepared from Techida kit is a colourless, sterile solution that contains radioactive isotope. Use of Techida is permitted only in departments of nuclear medicines.

^{99m}Tc-Techida injection is administered intravenously. After intravenous administration, ^{99m}Tc-Techida is transported to the liver via the blood circulation. As the medicine contains gamma-radiator radioactive isotope, it can be detected from outside the body using gamma cameras. The pictures taken by this camera show the distribution of the radioactive isotope in your body and organs. The pictures can give your doctor valuable information about the structure and working of the liver, gallbladder and duodenum helping this way to choose the best treatment.

2. BEFORE YOU USE TECHIDA

Do not use Techida

- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of Techida.
- If you are pregnant or breast feeding, except if your doctor decides otherwise
- If you are under 18 years of age, except if your doctor decides otherwise

Make sure you carry out the doctor's instructions both before and after the examination in order to avoid radioactive exposure of other people and the radioactive contamination of the environment.

The radioactive isotope is excreted in the urine, faeces, sweat and other secretions temporarily contaminating the environment this way.

If you have any further questions on the use of this medicine, ask your doctor.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

No interactions with other medicines are known.

Using Techida with food and drink

You can take Techida with any food or drink.

Pregnancy and breast-feeding

It is important to tell your doctor if there is any possibility that you are pregnant or if you breast-feed.

In these cases your doctor will consider the necessity of the radioisotope diagnostics. The radioisotope can be dangerous to the foetus and the infant, and it is excreted in breast milk. Therefore, it is possible that your doctor will choose other, non-radioactive method. Trust your doctor, because the decision will be made in accordance with strict regulations.

If you are breast-feeding and you will be examined with this product, you should stop breast-feeding for the period recommended by your doctor.

During this time the radioactive isotope will be eliminated from your body.

Use formula feed for your child. The breast milk should be expressed and collected and spilled out after dilution. You can restart breast-feeding when the radiation dose for the child is less than 1 mSv. Your doctor will decide about the restart of breast -feeding.

Driving and using machines

^{99m}Tc-Techida has no influence on the ability to drive and use machines.

Important information about some of the ingredients of TECHIDA

When you are given ^{99m}Tc- Techida you receive a small amount of radiation. The adsorbed dose in this case is usually smaller than those of certain X-ray examinations (e.g. CT). Your doctor will always consider the possible risks and advantages.

If you have any further questions on the use of this medicine, ask your doctor.

3. HOW TO USE TECHIDA

^{99m}Tc- Techida injection is prepared by mixing the content Techida kit and radioactive ^{99m}Tc-pertechnate at the site of the use (hospitals, clinics). The injection is administered intravenously.

Amount of the administered activity, method and timing of imaging is decided by your doctor according to the type of examination and your state of health.

What should you do if you received overdose of the medicinal product?

There are strict rules and regulations on handling, use and disposal of radioactive materials. Therefore, ^{99m}Tc- Techida can only be used in hospitals or institutes.

Techida can be handled, used and administered only by people specialized for handling of radioactive materials and waste. These people give you instructions about the precautions and warnings. Comply with their instructions.

Since ^{99m}Tc-Techida is given by a doctor under controlled conditions, the probability of overdose is low. In the unlikely event of overdose your doctor will advise you to drink lots of liquid which will accelerate the elimination of the drug from your body. You should take all necessary precautions against the contamination of your environment with radioactivity. Comply with the instructions given by your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like every medicinal product, Techida might cause adverse reactions, but such effects do not appear in every case. If any adverse reaction becomes serious, inform your doctor.

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 applied amount of activity.

Adverse event and reactions have not been reported ever since the authorization of the product (1985). Considering the number of the examinations carried out since, no adverse reactions are expected (frequency lower than 1/10000).

5. HOW TO STORE TECHIDA

Keep out of the reach and sight of children and people who are not authorized to handle, use or transport this product!

Hospital staff will ensure that the product is stored correctly and not used after expiry date stated on the label.

Techida powder for injection should be stored in refrigerator at 2-8 °C in its original packaging.

Radioactive ^{99m}Tc- Techida is to be stored below 25°C, considering the regulations for radiation safety.

^{99m}Tc-labelled Techida must be used within 3 hours.

6. FURTHER INFORMATION

What Techida contains

- The active substance is 30 mg N-(2,6-diethyl-acetamidil)-imino diacetic acid
- Other ingredients are: Stannous chloride dihydrate, Ascorbic acid, sodium chloride
- The active substance of the labelled, radioactive Techida: ^{99m}Tc-Techida

What Techida looks like and contents of the pack

The injection vials (6 ml) containing the sterile, pyrogen-free freeze-dried product are closed with rubber stopper and tear-off komicap (aluminium and plastic).

Six vials of Techida powder for injection are packed into one paper box, with six label with radioactive symbol.

Marketing Authorisation Holder and Manufacturer

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