**Gamma camera images of the liver – spleen tract can be taken.**

**Method of examination**

- The table of Chapter 11 contains absorbed radiation dose data in µGy Tc-Fyton.

**Excipients**

- Stannous chloride dihydrate 1.0 mg Reducing agent
- Sodium-chloride 10.0 mg Filler

**Incompatibilities**

- 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 of Chapter 12.

**Use of the product is contraindicated in case of pregnancy and lactation.**

**Pharmacokinetic properties**

- The liver uptake is quick, it can be observed even some minutes after administration. After thirty minutes 90% of the radioactivity is accumulated in the liver. However, these live diseases result in an increased spleen activity.

**Pharmacological properties**

- The liver uptake is quick, it can be observed even some minutes after administration. After thirty minutes 90% of the radioactivity is accumulated in the liver. However, these live diseases result in an increased spleen activity.

**Pharmacodynamic properties**

- The liver uptake is quick, it can be observed even some minutes after administration. After thirty minutes 90% of the radioactivity is accumulated in the liver. However, these live diseases result in an increased spleen activity.

**Pharmacotherapeutic group**

- Radio-pharmaceuticals

**ATC code**

- V02BA01

**Function**

- Therapeutic

**INDICATION FIELD: ISOTOPE DIAGNOSTICS**

- Morphological examination of the liver by imaging technique –Diagnosis of benign and malignant liver tumours and monitoring the course of the disease

**Posology**

- Use of the product is contraindicated in case of pregnancy and lactation. In case of intravenous administration of 1 MBq of Tc-Fyton, the mean radiation dose in the liver can be calculated on 70 kg average bodyweight level (calculated on 70 kg average bodyweight). This is equivalent to 0.25% of the not observed reference level. Thus, no risk of radiation is associated with the radiation exposure.

- One component of Fyton kit is sodium-chloride, which is a non-radioactive component, therefore the risk of radiation exposure is negligible.

**Preclinical safety data**

- 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 of Chapter 12.

**Special precautions for disposal and other handling**

- Any unused product or waste material should be disposed of in accordance with local requirements.
8. MARKETING AUTHORISATION NUMBER(S)

OGYI-T-9288.01

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 December 1977 / 18 December 2009

10. DATE OF REVISION OF THE TEXT

18 December 2009

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

11. DOSIMETRY

Individual patient dose is 74 – 185 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.

<table>
<thead>
<tr>
<th>Organ</th>
<th>Absorbed dose [µg / MBq]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver</td>
<td>92</td>
</tr>
<tr>
<td>Spleen (at spleen scintigraphy)</td>
<td>57</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>7.3</td>
</tr>
<tr>
<td>Tests</td>
<td>0.3</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
</tr>
</tbody>
</table>

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Remove the protective foil and lift up the upper part of the paper box to access the vials. The Fyton kit can only be administered to patient after labelling with 99mTc. Never administer Fyton kit without performing the labelling.

100% 99mTc-Tc-Fyton injection contains radioactive isotope. For handling, shipping and storage of this product besides pharmaceutical regulations 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 5 mm. Under aseptic circumstances inject 0.8 – 1.6 GBq of sterile sodium pertechnetate into the vial through the rubber stopper with a sterile syringe. This solution can be used for intravenous administration.

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

Control of drug product

Product of radiochemical purity of 99mTc-Tc-Fyton is tested by using paper chromatography. Method: Stationary phase: Whatman ET31 (catalogue code: 3031915) 1.5x20 cm paper strips

1. WHAT FYTON IS AND WHAT IT IS USED FOR

This medicine is for diagnostic use only.

100% 99mTc-Tc-Fyton injection prepared from Fyton kit is a sterile solution that contains radioactive isotope. Use of 99mTc-Tc-Fyton is permitted only in departments of nuclear medicine.

99mTc-Tc-Fyton injection is administered intravenously. After intravenous administration, 99mTc-Tc-Fyton is transported to the liver via the blood circulation. As the medicine contains gamma-radiation or 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 organ helping this way to choose the best treatment.

99mTc-Tc-Fyton is suitable for morphological examination of the liver, diagnosis of benign and malignant liver tumours and monitoring of the therapy.

1.5x20 cm paper strips

Mobile phase: Acetone, 10 % CaCl₂ solution. Temperature: Room temperature: 20-25°C.

From prepared 99mTc-Tc-Fyton injection is tested by two chromatographic processes:

- Determination of free 99mTc-Tc: by paper chromatography
  Use 3 pieces of 1.5 x 20 cm ET-31 paper strips. Apply to the strips 5 – 5 µl (approximately 1 MBq/ml) of the solution to be tested at 1.5 cm from the end of the paper. Develop the strips over a 1.5 cm path in acetone. Extraction: Dry the strips and impregnate them with 5% polysoyene solution. Determine the radioactivity by using a scanner. Radiochemical purity is calculated by using the data of the three replicates.

- Determination of radiochemical purity formed with Ca₃(PO₄)₂ ions by paper chromatography
  Use 3 pieces of 1.5 x 20 cm ET-31 paper strips. Apply to the strips 5 – 5 µl of the solution to be tested at 1.5 cm from the end of the paper. Develop the strips over a 1.5 cm path in 10% CaCl₂. Dry the strips and impregnate them with 5% polysoyene solution. Determine the radioactivity by using a scanner. Radiochemical purity is calculated by using the data of the three replicates.

Information on Rf values:

99mTc-Tc-fyton and Ca-siopepsin system 0.3-0.4
Free 99mTc-EO- 0.7-1.0
Radiochemical purity is calculated by using the peak areas. Total activity of the strip is considered 100% and activity percentage due to 99mTc-Tc-Fyton peak is the radiochemical purity, which is not less than 90% at expiry date.

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

1.5x20 cm  paper strips

Package leaflet: Information for the user

Fyton 15 mg powder for injection
Sodium phytate

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

1. WHAT FYTON IS AND WHAT IT IS USED FOR

This medicine is for diagnostic use only.

100% 99mTc-Tc-Fyton injection prepared from Fyton kit is a sterile solution that contains radioactive isotope. Use of 99mTc-Tc-Fyton is permitted only in departments of nuclear medicine.

99mTc-Tc-Fyton injection is administered intravenously. After intravenous administration, 99mTc-Fyton is transported to the liver via the blood circulation. As the medicine contains gamma-radiation or 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 organ helping this way to choose the best treatment.

99mTc-Tc-Fyton is suitable for morphological examination of the liver, diagnosis of benign and malignant liver tumours and monitoring of the therapy.

2. BEFORE YOU USE FYTON

Do not use Fyton

- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of Fyton;
- 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;
- if you have any further questions on the use of this medicine, ask your doctor.

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

Using other medicines

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

Using Fyton with food and drink

You can take Fyton 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-feeding. 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 mother’s 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 radioisotope will be eliminated from your body. Use formula feed for your child. The breast milk should be expressed and kept out of the reach and sight of children and people who are not authorized to handle, use or transport this product. Keep out of the reach and sight of children and people who are not authorized to handle, use or transport this product.

Protection of the environment

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

Adverse reactions

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 18.12.2009.