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the data of three replicates.
Information on Rf values: ^{99m}Tc-Fyton complex: 0–0.3, Free ^{99m}TcO4- 0.8–1

-Examination of the disperse system formed with Ca^{++} 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 15 cm path in 10% $CaCl_2$. Dry the strips and impregnate them with 5% polystyrene solution. Determine the radioactivity by using a scanner. Radiochemical purity is calculated by using the data of three replicates.
Information on Rf values:
^{99m}Tc-phytate and Ca disperse system 0.3–0.4
Free ^{99m}TcO4- 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 ^{99m}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 requirements.

IZOTOP

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

This medicine is for diagnostic use only.
^{99m}Tc-Fyton injection prepared from Fyton kit is a sterile solution that contains radioactive isotope. Use of Fyton is permitted only in departments of nuclear medicines.
^{99m}Tc-Fyton injection is administered intravenously. After intravenous administration, ^{99m}Tc-Fyton is transported to the liver via the blood

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.

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 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-Fyton has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Fyton

When you are given ^{99m}Tc-Fyton 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 FYTON

^{99m}Tc- Fyton injection is prepared by mixing the content Fyton 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?

4. POSSIBLE SIDE E

Exposure to ionising radiatic
potential for development of
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Adverse event and reactions
authorization of the product
examinations carried out sin
The amount of radioactivity
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you have any further questio
doctor.

5. HOW TO STORE

Keep out of the reach and sig
authorized to handle, use or
Hospital staff will ensure tha
used after expiry date stated
Fyton powder for injection s
Radioactive ^{99m}Tc- Fyton is
regulations for radiation safe
^{99m}Tc-labelled Fyton must b
Expiry and storage condition

6. FURTHER INFO

What Fyton contains
- The active substance
- Other ingredients are chloride
- The active substance Fyton

What Fyton looks like and

The injection vials (6 ml) co
dried product are closed with
(aluminium and plastic).
Six vials of Fyton kit are pac
radioactive symbol.

Marketing Authorisation H

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Tel.: 36 1 391 0859; 36 1 39
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E-mail: ragyo@izotop.hu

This leaflet was last appro

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Organ-specific chelating agent of ^{99m}Tc radioisotope

injection
vial Function

Organ-specific diagnostic information

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action can be divided to
Fyton kit by using 0.8 –

- Pregnancy and lactation
- Under 18 years of age except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure

4.4 Special warnings and precautions for use

Patient exposure must be minimised, i.e. the possible lowest activity should be used for the examination to obtain the diagnostic results.
Radioactive medicinal products should be received, used and administered only by authorised person in designated clinical settings.
Receipt, storage, use, transfer and disposal of the radioactive medicinal products are subject to the regulations and appropriate licences of the competent authorities.

4.5 Interaction with other medicinal products and other forms of interaction

No drug-drug interactions have been described to date.

4.6 Pregnancy and lactation

Use of the product is contraindicated in case of pregnancy and lactation.
There are no information on the secretion of ^{99m}Tc-phytate in breast milk. Therefore, use of the product is contraindicated in case of breast feeding mother.

4.7 Effects on ability to drive and use machines

The product has not direct influence on ability to drive and use machines.
In occurrence of unexpected adverse reactions driving and/or working with machines should be reconsidered.

4.8 Undesirable effects

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 (1977) nor registered in the literature.
Considering the number of the examinations carried out since, no adverse reactions are expected (frequency lower than 1/10000).
The effective dose remains below 20 mSv even in case of the maximal advised dose.

4.9 Overdose

of Fyton is introduced in the body.
Acute toxicity studies on rats showed that there are not any clinical symptom, if less than 4 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 0.21 mg/kg of bodyweight level (calculated on 70 kg average bodyweight). This is equivalent to 5.25 % 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: Radiopharmaceuticals
ATC code: V09D B 07
After administered intravenously ^{99m}Tc-phytate forms a microdisperse system (colloid) with calcium ions of the blood. The cells of the liver and the spleen, the Kupffer-cells and the reticuloendothelial system extract that system from the blood (phagocytosis). 90-95% of the activity appears in the liver. Further 5-10% is deposited in the spleen and the bone marrow. The colloid leaves the liver in the way of slow degradation and hydrolysation of the micro-particles.
In case of impaired liver function the bone marrow radioactivity is increased and some activity appears in the lungs. However, diffuse liver diseases result in an increased spleen activity.

5.2 Pharmacokinetic properties

^{99m}Tc-phytate introduced intravenously leaves the bloodstream in two parallel processes described by two exponential curves:
Fast process $T_{1/2}$ = 2.4-7 min
Slow process $T_{1/2}$ = 69-105 min
The fast process is the result of the operation of the reticulo-endothelial system.
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, excretion from the liver is extremely slow.

5.3 Preclinical safety data

Acute toxicity study of rats showed no clinical symptoms up to 4 mg/kg of body weight. Quantity of the administered ^{99m}Tc-Fyton, if complying with the recommendations, is not less than 2.5 mg and not more than 5.0 mg. Calculated on an average 70 kg of bodyweight the smallest and the greatest quantities are equivalent to 0.9 and 1.8 % of the no observed effect level, respectively. Thus, the use of the product considered 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

Sodium-chloride

6.2 Incompatibilities

One component of Fyton reducing agent. It reduces state) to +4 oxidation stat complex with Fyton. It is the vials from moisture ar oxidation agents or oxyge the oxidation of Sn (II) be the product is incompatib As a result of these incom remove the closure of the labelling reaction. Perforr instructions of Chapter 12

6.3 Shelf life

Shelf life of Fyton kit (lyc in injection vials closed w kombicap) is 12 month fr One paper box contains 6 labelled at different times ^{99m}Tc-labelled Fyton mus

6.4 Special precautio

Do not store Fyton kit abc Do not store ^{99m}Tc-Fyton regulations for radiation s

6.5 Nature and conte

The injection vials of Fyt and freeze-dried compone are closed with rubber sto The labelled vials are sup carton box. Position of the carton insert, which preve contains six vials, one Su Patient Information Leafl material sign.

6.6 Special precautio

Any unused product or w accordance with local req