SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Pyron 25 mg powder for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition of Pyron powder for injection

Component	*Quantity per vial*	*Function*
Active substance		
Sodium pyrophosphate	25.0 mg	Organ-specific chelating agent of ^{99m}Tc radioisotope

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

Component	*Quantity per vial*	*Function*
Active substance		
^{99m}Tc-Pyron	1.3–3.0 GBq	Organ-specific diagnostic information

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
INDICATION FIELD: ISOTOPE DIAGNOSTICS
-Bone scintigraphy tests. Use of the product especially recommended in the following cases:
-Primer bone tumour.
-Bone metastases of other tumours (i.e. prostate cancer, breast cancer, lung cancer).
-Osteomyelitis.
-Metabolic bone diseases.
-Paget's disease.
-Imaging of acute myocardial infarct.
-Blood pool scintigraphy.
-Spleen scintigraphy.

4.2 Posology and method of administration

Posology
300-500 MBq ^{99m}Tc-Pyron for intravenous administration, depending on the test type.

Method of administration
Three different labelling procedures are available for ^{99m}Tc-Pyron depending on the type of the test.
Bone scintigraphy and acute myocardial infarct
^{99m}Tc-labelled pyrophosphate can be directly used for imaging. Content of Pyron injection vials should be labelled by using 1.3-3.0 GBq of ^{99m}Tc-pertechnate and the labelled preparation can be divided to 3-6 single doses. The recommended individual patient dose of ^{99m}Tc- pyrophosphate is 300-500 MBq.
For paediatric examination use Webster's equation, which is given below, to determine the activity to be administered and see Chapter 4.3. (Contraindications).

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

where N age of the child [year]
A_{child}, A_{adult} activity [MBq]

Blood pool scintigraphy:
Pretreat red blood cells in vivo as follows. Add 2-5 ml sterile 0.9% sodium-chloride solution to the content of Pyron injection vial. After dissolution divide it to 1-2 portions and administer intravenously to the patient. Wait 15-30 minutes and then administer intravenously to the patient 300-400 MBq of ^{99m}Tc-pertechnate obtained from a generator as eluent. This will label the red blood cells pretreated with pyrophosphate.
Spleen scintigraphy:
Pretreat red blood cells in vivo as follows. Add 2-5 ml sterile 0.9% sodium-chloride solution to the content of Pyron injection vial. After dissolution divide it to 3-6 portions and administer intravenously. Wait 15-30 minutes. After waiting time, take 10 ml blood into a sterile centrifuge tube containing anticoagulant (for example, heparin or sodium-citrate). To separate the red blood cells centrifuge the blood and remove the blood serum. Add 75-100 MBq ^{99m}Tc-pertechnate to the suspension in a volume equivalent to the volume of the suspension. Homogenise, then incubate the labelled red blood cells at 49.5°C for 20 minutes (degradation). Allow to cool to room temperature. Now, the labelled red blood cells, which accumulate in the spleen, are ready to be reinjected to the patient.
Method of examination
Recommended times for imaging by gamma camera or scanner are specified below.

Bone scintigraphy:	3-4 hours after administration
Acute myocardial infarct:	30-60 minutes after administration
Blood pool scintigraphy:	15 minutes after administration
Spleen scintigraphy:	30-60 minutes after reinjection

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Pregnancy and lactation (See section 4.6).
- Under 18 years of age, except if the necessity and importance of obtaining the diagnostic information outweighs the risk associated with the radiation exposure. In this case reduced amount of activity should be used. See 4.2.

4.4 Special warnings and precautions for use

^{99m}Tc-Pyron contains radioactive isotope. 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. Way of handling of radiopharmaceuticals should meet the criteria both of radiation safety and pharmaceutical quality requirements.
Use of the product is contraindicated for patients under 18 years of age (See section 4.2) except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.
Use of the product is contraindicated in case of pregnancy and lactation (See section 4.6) except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.

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 except if the necessity and importance of obtaining the diagnostic information outweights the risk associated with the radiation exposure.
When it is necessary to administer radioactive medicinal products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed pregnant until proven otherwise. Treatment of women of child bearing potential is recommended in the first 10 days after menstruation.

4.7 Effects on ability to drive and use machines

^{99m}Tc-Pyron does not have direct influence on abilities 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 (1982) nor registered in the literature. Considering the number of the examinations carried out since, no adverse reactions are expected (frequency lower than 1/10000).

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-Pyron. 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-Pyron administered to one patient is not less than 4.17 mg and not more than 12.5 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 25 mg of ^{99m}Tc-Pyron is introduced in the body.
Acute toxicity studies on mice showed no clinical symptoms if less than 5 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 0.357 mg/kg of bodyweight level (calculated on 70 kg average bodyweight). This is equivalent to 7.14% 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: V09BA03
After administered intravenously the labelled ^{99m}Tc-pyrophosphate, which behaves similarly to ^{99m}Tc-diphosphonates (e.g. methylene-diphosphonate, 1-hydroxy-ethylidene-1,1-diphosphonate), leaves the blood and concentrates mainly in the skeleton, but it visibly appears in the liver as well. The mechanism of the bone uptake is ion exchange and chemisorption in the inorganic matrix of the bone, in the ionic hydroxy-apatite [$Ca_{10}(PO_4)_6(OH)_2$]. Phosphate groups on the surface of the bone matrix take part in an ion exchange reaction with the free $-PO_3Na_2$ groups of pyrophosphate co-ordinated to technetium. This way radioactive ^{99m}Tc is bounded on the bone matrix. This process takes place in case of normal bone function as well as in case of altered bone function. However, adsorption is significantly more extensive at sites where the blood supply of the bone is increased, and the bone formation activity (osteoblast function) is increased.
Therefore, at sites of bone lesions (primer tumours, metastases, splitting and fractures of the bone, inflamed bone) increased radioactivity can be observed, which enables imaging.
A similar uptake mechanism is presumable in case of acute myocardial infarct. Calcium and phosphate build in the necrotic tissues, this offers the possibility of chemisorption of ^{99m}Tc-pyrophosphate. Since the calcium and phosphate infiltration is intensive only in case of infarcts not older than 72 hours, positive response can be obtained by imaging exclusively in such cases. To have an evaluable image the mass of the infarct should exceed 5 grams.
The reason of the appearance in the liver is that the enzymes of the liver split the P-O-P bonds in ^{99m}Tc-pyrophosphate and the complex compound transforms into reduced-hydrolysed technetium, which localises in the liver.
Approximately 45% of the intravenously administered ^{99m}Tc-pyrophosphate appears in the bone in the 4th hour after injection while 20% in the liver and 18% in the urine at the same time. Approximately 2% remains in the bloodstream, its 40% is bound to the red blood cells and 60% is present in the plasma.
However, stannous (II) pyrophosphate solution prepared from Pyron kit by dissolving the content of the vial in physiological saline has different pharmacological features. Stannous (II) pyrophosphate forms an adduct in two cases: 1) in vitro with the red blood cells separated from the blood 2) in vivo in case of intravenous administration. The ^{99m}Tc-pyrophosphate complex forms in vivo in the red blood cell – stannous (II) pyrophosphate adduct, therefore, more then 90% of the intravenously administered ^{99m}Tc-pertechnate is localised in the red blood cells. On the other hand, ^{99m}Tc-pyrophosphate-labelled and heat-treated reinjected red blood cells are accumulated in the spleen after reinjection.

5.2 Pharmacokinetic properties

50% of ^{99m}Tc-pyrophosphate administered intravenously leaves the bloodstream in 38 minutes, 83% in 4 hours. Meanwhile, 45% of the activity appears in the bones, 20% in the liver and 18% is excreted via the kidneys.
In case of myocardial infarct not older than 72 h, ^{99m}Tc-pyrophosphate localises in the necrotic tissues in 30-60 minutes, depending on the quantity and size of the necrotic tissues.
Intravenously administered stannous (II) pyrophosphate not labelled with radioisotope is localised in the red blood cells in 10-15 minutes. 96% of ^{99m}Tc-pertechnate injected thereafter appears in the red blood cells in 5 minutes and is still in bound state after 1 hour.
Red blood cells, which were previously labelled in vitro and degraded, are almost exclusively present in the spleen 30 minutes after reinjection.

5.3 Preclinical safety data

Acute toxicity study on mice showed no clinical symptoms up to 5 mg/ kg of bodyweight. Quantity of ^{99m}Tc-Pyron, if administration is complying with the recommendations, is not less than 4.17 mg and not more than 12.5 mg . If the whole content of the vial containing the labelled substance is administered to one patient by mistake, it represents 0.357 mg/kg of bodyweight level (calculated on 70 kg average bodyweight). This is equivalent to 7.14 % of the no observed effect level. 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, which is in the range of 1.3-3.0 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

Component	*Quantity per vial*	*Function*
Excipients		
Stannous chloride dihydrate	1.0 mg	Reducing agent of [^{99m}Tc]pertechnetate
Sodium chloride	10.0 mg	Filler

6.2 Incompatibilities

Stannous chloride component of Pyron kit is a reducing agent. It reduces free pertechnetate from +7 oxidation state to +4 oxidation state, in which technetium readily forms complex with Pyron. 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.

6.3 Shelf life

Shelf life of Pyron kit (lyophilised, non-radioactive components in injection vials closed with rubber stopper and aluminium kombicap) is 12 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 Pyron must be used within 3 hours.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

The labelled 6 ml injection vials are closed with rubber stopper and tear-off aluminium kombicap. One box contains six vials, one Summary Of Product Characteristic and Patient Information Leaflet and six labels with radioactive material sign.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

Institute Of Isotopes Co. Ltd.
Addresse: 1121 Budapest, Konkoly Thege Miklós str. 29-33.
✉ 1535 Budapest, P.O.B. 851.
Tel.: 36 1 391 0859
Fax: 36 1 395 9070
E-mail: commerce@izotop.hu

8. MARKETING AUTHORISATION NUMBER(S)

OGYI-T-9246/01

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 January 1982 / 22 December 2009

10. DATE OF REVISION OF THE TEXT

07 October 2015

This SPC was translated by the manufacturer based on the original Hungarian document, authorized by the Hungarian National Institute of Pharmacy on 07.10.2015.

11. DOSIMETRY

Individual patient dose is 300-500 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]
Skeleton	12.2
Kidneys	1.6
Urinary bladder	13.3
Liver	3.3
Spleen (at spleen scintigraphy only)	5.4
Whole body	2.7

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	–	–

During the decay ^{99}Tc is produced.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

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

Bone scintigraphy and acute myocardial infarct tests

Only ^{99m}Tc-labelled pyrophosphate can be administered to the patient.

^{99m}Tc- Pyron is a solution containing radioactive isotope. For handling, shipping and storage of this product the rules and regulations referring to the radioactive materials should be observed.

Radioactive labelling reaction is to be carried out as follows.

Place one vial containing the freeze-dried powder in a small lead pot of 3 mm wall thickness . Inject 2-5 ml of sterile ^{99m}Tc - pertechnetate (1.3-3.0 GBq) into the vial through the rubber stopper with a sterile syringe under aseptic circumstances. Shake well and allow standing at room temperature for 15 minutes. The obtained ^{99m}Tc-labelled pyrophosphate can be administered intravenously. pH of the labelled preparation is in the range of pH=5.0-7.0. The solution should be used within 3 hours from labelling. Within this period the quantity of the radiochemical impurities does not exceed 10%.

Blood pool scintigraphy

For blood pool scintigraphy content of Pyron vial is dissolved in physiological saline and administered to patient directly.

Red blood cells should be pretreated in vivo as follows. Dissolve the content of Pyron injection vial in 2-5 ml of 0.9% sodium chloride solution, divide it 1-2 single dose and administer intravenously. After 15-30 minutes, administer intravenously 300-400 MBq ^{99m}Tc-pertechnetate obtained as generator eluate to the patient. This labels the red blood cells pretreated with pyrophosphate.

Spleen scintigraphy

For spleen scintigraphy content of Pyron vial is dissolved in physiological saline and administered to patient directly.

Pretreat red blood cells in vivo as follows. Add 2-5 ml sterile 0.9 sodium-chloride solution to the content of Pyron injection vial. After dissolution divide it to 3-6 portion and administer intravenously. Wait 15-30 minutes.

After waiting time, take 10 ml blood into a sterile centrifuge tube containing anticoagulant (for example, heparin or sodium-citrate). To separate the red blood cells centrifuge the blood and remove the blood serum. Add 75-100 MBq ^{99m}Tc-pertechnate to the suspension in a volume equivalent to the volume of the suspension. Homogenise, then incubate the labelled red blood cells at 49.5°C for 20 minutes (degradation). Allow to cool to room temperature. Now, the labelled red blood cells, which accumulate in the spleen, are ready to be reinjected to the patient.

The labelled preparation should be used within 3 hours from labelling. Within this period the quantity of the radiochemical impurities does not exceed 10%.

Control of the drug product

Radiochemical purity of the Injection: Ph. Eur. 2.2.27.

Preparation of Injection: use the eluate of a ^{99m}Tc generator for labelling. Inject the ^{99m}Tc eluate which has an activity between 0.8-1.6 GBq – in no more than 3 ml volume – into a vial using a disposable sterile syringe and needle without removing its cap. Shake it regularly and allow 15 minutes for the complexation reaction to finish. Label one vial and develop three parallel chromatograms.

Test "A" (determination of the ratio of reduced, hydrolyzed ^{99m}Tc): prepare 3 pieces of 1.5cm×15cm strips from ITLC-SG chromatographic layer previously heated at 110°C for 10 minutes. Mark the start point from 1.5 cm from the end of the strip. Using a pipette apply 5 µl of labelled product to the start point. Don't let the spot dry in air. Develop the chromatograms immediately in 136 g/L (1M) sodium-acetate as eluent till the front distance of 10 cm has reached. After removing the strips from the tank, dry them in air and impregnate with 5% polystyrene solution. After the polystyrene coating has dried, record the chromatogram by gamma scanner. Expected R_f values are:

Reduced, hydrolyzed ^{99m}Tc 0.0 – 0.1
Labelled complex and free $^{99m}TcO_4^-$ 0.9 – 1.0

Test "B" (Determination of the ratio of free pertechnetate): prepare 3 pieces of 1.5cm×15cm strips from ITLC-SG chromatographic layer previously heated at 110°C for 10 minutes. Mark the start point from 1.5 cm from the end of the strip. Using a pipette apply 5 µl of labelled product to the start point. Let the spot dry in air. After the spot has dried, develop the chromatograms in methyl ethyl ketone solution, till the front distance of 10 cm has reached. After removing the strips from the tank, let them dry in air and impregnate them with 5% polystyrene solution. After the polystyrene coating has dried, record the chromatogram by gamma scanner. Expected R_f values are:
Labelled complex and reduced, hydrolyzed ^{99m}Tc 0.0 – 0.1
Free $^{99m}TcO_4^-$ 0.95 – 1.0

Specification: radiochemical purity is not less than 90%.

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

IZOTOP

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pyron 25 mg powder for injection
Sodium pyrophosphate

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 PYRON IS AND WHAT IT IS USED FOR

This medicine is for diagnostic use only.
Use of Pyron is permitted only in departments of nuclear medicines.
-Bone scintigraphy tests. Use of the product especially recommended in the following cases:
-Primer bone tumour.
-Bone metastases of other tumours (i.e. prostate cancer, breast cancer, lung cancer).
-Osteomyelitis.
-Metabolic bone diseases.
-Paget's disease.
-Imaging of acute myocardial infarct.
-Blood pool scintigraphy.
-Spleen scintigraphy.

The medicine is administered intravenously and is transported to the different organs 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 organ helping this way to choose the best treatment.

2. BEFORE YOU USE PYRON

Do not use Pyron
- if you are allergic (hypersensitive) to the active substance or any of the other ingredients of Pyron,
- 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.

Using Pyron with food and drink
You can take Pyron with any food or drink.

Pregnancy and breastfeeding
It is important to tell your doctor if there is any possibility that you are pregnant or if you breastfeeding.
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 breastfeeding when the radiation dose for the child is less than 1 mSv. Your doctor will decide about the restart of breastfeeding.

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

Important information about some of the ingredients of Pyron
When you are given ^{99m}Tc-Pyron 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 PYRON

Use of Pyron depends on the method of examination

In case of bone scintigraphy and acut myocardial infarctus
Pyron powder for injection is used to prepare radioactive ^{99m}Tc-Pyron solution for injection, which is administered intravenously to you.

In case of blood pool scintigraphy
1. Non-radioactive Pyron injection is administered to you.
2. After 15-30 minutes injection containing radioactive isotope is administered to you.

Examination of the spleen
1. Non-radioactive Pyron injection is administered.
2. Blood sample is taken from you, red blood cells of this sample are labelled with radioactive isotope.
3. Injection containing the labelled red blood cells are administered to you.

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-Pyron can only be used in hospitals or institutes.
Pyron 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-Pyron 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 and eat lots of high-fiber foods 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

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 (1982). Considering the number of the examinations carried out since, no adverse reactions are expected.
The amount of radioactivity in the body from ^{99m}Tc-Pyron is small. It will be passed out of the body in a few days without any intervention. If you have any further questions on the use of this medicine, ask your doctor.

5. HOW TO STORE PYRON

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.
Pyron powder for injection should not be store above 25°C.
Radioactive ^{99m}Tc-Pyron is to be stored below 25°C. Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

6. FURTHER INFORMATION

What Pyron contains
- The active substance is 25 mg sodium pyrophophyate per vial.
- Other ingredients are: stannous chloride dihydrate, sodium chloride.
- The active substance of the labelled, radioactive Pyron: ^{99m}Tc-pyrophosphate.

What Pyron 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 kombicap (aluminium and plastic).
Six vials of Pyron kit are packed into one paper box, with six label with radioactive symbol.

Marketing Authorisation Holder and Manufacturer

Institute Of Isotopes Co. Ltd.
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