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

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Quantity per vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium pertechnate</td>
<td>250 mg</td>
</tr>
</tbody>
</table>

Composition of 99mTc-Pyron radioactive composition

Component

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Quantity per vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tc-99m</td>
<td>1.3–3.0 GBq</td>
</tr>
</tbody>
</table>

For a full list of excipients, see section 6.1.

3. PHARMACOLOGICAL PROPERTIES

Pharmaceutical form of Pyron kit: powder for injection (lyophilisate).

Pharmaceutical form of 99mTc-Pyron: injection.

- 99mTc-Pyron injection can be prepared in sites at the site of the use i.e. at isotope laboratories of clinics or hospitals. The powder from the Pyron powder for injection (lyophilisate in the vial) and 99mTc-pertechnetate eluate. Sterile, pyrogen free solution of 99mTc-pertechnetate can be obtained using 99mTc-Generator.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Bone scintigraphy: Diagnostic scintigraphy is the most widespread and popular method in medicine of visualising bones and detecting bone metastases of other tumours (i.e. prostate cancer, breast cancer, lung cancer).

Spleen scintigraphy: The size of the spleen is determined in cases of splenomegaly (e.g. in lymphoses, infectious mononucleosis).

Bone metastases of other tumours (i.e. prostate cancer, breast cancer, lung cancer).

Pyron is introduced in the body.

Acute toxicity studies on mice showed no clinical symptoms up to 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 25 mg of 99mTc-Pyron is introduced in the body.

Intravenously administered stannous (II) pyrophosphate not labelled with radioisotope is localised in the red blood cells in 10–30 minutes. 99mTc-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 99mTc-Pyron is introduced in the body.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacokinetic properties

Pharmacotherapeutic group: Diagnostic radio pharmaceutical, ATC code: V09B04a. Adherence to dissolution rules of Pyron kit according to the instructions detailed in Chapter 4.3. Adherence to dissolution rules of Pyron kit according to the instructions detailed in Chapter 4.3.

5.2 Preclinical safety data

Acute toxicity study on mice showed no clinical symptoms up to 5 mg/kg of bodyweight.

5.3 Pharmacokinetic properties

When it is necessary to administer radioactive medicinal products to women of childbearing age of the child [year]

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Component

<table>
<thead>
<tr>
<th>Quantity per vial</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excipients</td>
<td></td>
</tr>
<tr>
<td>Stannous chloride</td>
<td>1.0 mg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>10.0 mg</td>
</tr>
</tbody>
</table>

6.2 Incompatibilities

Stannous chloride solution of Pyron kit is a reducing agent. It reduces free pertechnetate from 7 oxidation state to 4 oxidation state, in which technetium Tc 99m 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 that are necessary to keep the Pyron kit powder for injection in a dry place.

7. MARKETING AUTHORISATION HOLDER

Institute Of Isotopes Co Ltd.

Address: 1121 Budapest, Konkoly Thege Miklós str. 29-33.

1355 Budapest, P.O. Box 851.

Tel: 36 1 391 0859

Fax: 36 1 395 9070

E-mail: commerce@iotophu.hu

8. MARKETING AUTHORISATION NUMBER(S)

OGYV-T-0462-01

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.
In this leaflet

- 1. What Pyron is and what it is used for
- Before you use Pyron
- How to use Pyron
- Possible side effects
- How to dispose of waste
- Further information

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.
  - Metastases of other tumours (i.e. prostate cancer, breast cancer).
  - Osteomyelitis.
  - Metabolic bone diseases.
  - Paget’s disease.
  - Imaging of acute myocardial infarction.
  - Blood pool scintigraphy.
  - Brain 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 image taken by this camera will 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 excipients.
- 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, 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 are 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.

The radioisotope will be excreted from your body and it is possible to take breast milk.

Use formula feed for your child. The breast milk should be expressed and cooled and spilled out after dilution. You can restart breast-feeding when the radiation dosage rate in breast milk will be reduced to less than 1 mBq. Your doctor will decide about the restart of breast-feeding.

Driving and using machines

No 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 Pyron you receive a small amount of radiation. The absorbed 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:
- Imaging of acute myocardial infarction.
- Bone scintigraphy (radioactive bone imaging).
- Imaging of acute myocardial infarction.
- Blood pool scintigraphy.
- Brain scintigraphy.

In case of blood pool scintigraphy

1. Non-radioactive Pyron injection is administered to you.
2. After 15-30 minutes injecting radioactive isotope is administered to you.

Examination of the spleen

1. Non-radioactive Pyron injection is administered.
2. Blood cells 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?

Take any strict rules and regulations on handling, use and disposal of radioactive materials. Therefore, 99mTc-Pyron can only be used in strict conditions.

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

Since 99mTc-Pyron is given by a doctor under controlled conditions, the probability of overdose is low. In the unlikely event that 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 99mTc-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.

HOSPITAL INSTRUCTIONS

Keep out of the reach of sight and children who are not under careful supervision. Children should carry an identification card showing that he or she is being examined with radioactive material. Hospital staff will ensure that the product is stored correctly and not used until expiration date on the label.

Pyron powder for injection should not be store above 25°C.

99mTc-Pyron is to be stored below 25°C. Storage of radioactive materials should be in accordance with national regulations on radioactive materials.

FURTHER INFORMATION

What Pyron contains

- The active substance is 25 mg sodium pyrophosphate per vial.
- Other ingredients are: stannous chloride dihydrate, sodium chloride.
- The active substance of the labelled, radioactive Pyron: 99mTc-pyrophosphate.

What Pyron looks like and contents of the pack

The injection vials (6 ml) containing the sterile, pyrogen-free freeze-dried pyrophosphate powder with rubber stopper and tear-off leotok (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

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