

# TechneScan PYP 20 mg

## Kit for radiopharmaceutical preparation,

sodium pyrophosphate decahydrate

Read all of this leaflet carefully before you are given this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

1. What TechneScan PYP is and what it is used for
2. What you need to know before TechneScan PYP is used
3. How TechneScan PYP is used
4. Possible side effects
5. How TechneScan PYP is stored
6. Content of the pack and other information

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## 1. WHAT TECHNE SCAN PYP IS AND WHAT IT IS USED FOR

This medicine is a radiopharmaceutical product for **diagnostic use only**.

TechneScan PYP is used through a scan to examine the:

- **spleen**
- **heart function**
- **blood flow** through the organs
- **hidden abdomen or bowel bleeding**
- **blood volume**

This medicine is a non-radioactive powder. When prepared by qualified people, it is used to induce a "stannous loading" of red blood cells prior to the use of radioactive solution of sodium pertechnetate ( $^{99m}\text{Tc}$ ) required for the labelling of red blood cells. When injected into the body, it collects in certain organs such as, the spleen or red blood cells.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the organ and body. This also gives the doctor valuable information about the structure and function of that organ.

The use of TechneScan PYP followed by sodium pertechnetate ( $^{99m}\text{Tc}$ ) does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

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## 2. WHAT YOU NEED TO KNOW BEFORE TECHNE SCAN PYP IS USED

TechneScan PYP **must not be used**:

- if you are allergic to sodium pyrophosphate decahydrate or any of the other ingredients of this medicine (listed in section 6).

### Warnings and precautions

**Take special care with TechneScan PYP:**

- if you are pregnant or believe you may be pregnant;
- if you are breast feeding;
- if you have a kidney disease.

**Before administration of TechneScan PYP you should:**

- drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study.

### Children and adolescents

Talk to your nuclear medicine doctor if you are under 18 years old.

### Other medicines and TechneScan® PYP

Tell your nuclear medicine doctor if you are taking or have recently taken or might take any other medicines since they may interfere with the interpretation of the images.

The following **medicines/materials can influence the TechneScan PYP examination**:

- medicines to prevent blood clotting such as **heparin**
- **tin** based medicines
- **aluminium** based stomach acid binding medicines
- medicines to lower blood pressure, such as **prazosin, methyldopa, hydralazin, verapamil, nifedipine**
- medicines to treat heart problems such as
  - **quinidine**
  - medicines with active substances names ending in "olol" such as **propranolol**
  - **digitoxin** or similar medicines
  - **nitrates**, such as nitroglycerin
- **certain medicines to treat cancer**, usually with active substance names ending in "rubicin"
- **iodine based contrast media**
- **teflon catheters**

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of TechneScan PYP, if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor, who will supervise the procedure.

### If you are pregnant

The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

### If you are breast-feeding

Tell your nuclear medicine doctor, as he/she will advise you to stop breast-feeding until the radioactivity has left your body. This takes about 4 or 12 hours depending on the radiolabelling procedure.

The expressed breastmilk during this period should be discarded. Please ask your nuclear medicine doctor when you can resume breast-feeding.

Moreover, you may need to avoid close contact with your baby during 2 hours after the procedure.

#### Driving and using machines

It is considered unlikely that TechneScan PYP will affect your ability to drive or to use machines.

#### TechneScan PYP contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

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### 3. HOW TECHNESCAN PYP IS USED

There are strict laws on the use, handling and disposal of radiopharmaceutical products. TechneScan PYP will only be used in a specialised, controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of TechneScan PYP to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult ranges from 1-925 MBq (megabecquerel, the unit used to express radioactivity), which is injected into a vein. This may be done directly (*in vivo* labelling method) or after being mixed with a sample of your blood (*in vitro* labelling method).

#### Use in children and adolescents

In children and adolescents, the quantity to be administered will be adapted to the child's weight.

#### Administration of TechneScan PYP and conduct of the procedure

TechneScan PYP is administered by intravenous injection followed by sodium pertechnetate (<sup>99m</sup>Tc) injection 30 minutes later (*in vivo* labelling method).

TechneScan PYP could also be added into a sample of your blood and mixed with sodium pertechnetate (<sup>99m</sup>Tc) solution. Your radiolabelled red blood cells are then reinjected into a vein.

One injection of TechneScan PYP is sufficient to conduct the test that your doctor needs.

#### Duration of the procedure

The nuclear medicine doctor will inform you about the usual duration of the procedure.

#### After administration of TechneScan PYP, you should

- avoid any close contact with young children and pregnant women for the 2 hours following the radiolabelling procedure.
- urinate frequently to eliminate the product from your body.

Repeat procedures are not recommended earlier than 3 months, as tin part of this medicine remains in the red blood cells for longer periods.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

#### If you have been given more TechneScan PYP than you should

An overdose is unlikely because you will only receive a single dose of TechneScan PYP precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the procedure may recommend that you drink plenty of water and void frequently to remove the traces of radioactivity from your body. Should you have any further question on the use of TechneScan PYP, please ask the nuclear medicine doctor, who supervises the procedure.

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### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects with frequency not known (cannot be estimated from the available data):

#### Allergic reactions:

- flushing
- general itching, hives, redness
- widening of blood vessels causing a drop in blood pressure
- sweating
- swelling of the arm or of the face
- nausea, vomiting
- fast heartbeat
- unconsciousness
- shortness of breath
- difficulty in swallowing
- muscle spasms and pain
- excessive tears
- taste disturbances

#### Vasovagal reactions:

- fainting
- headache, dizziness
- confusional state
- flow heartbeat
- ringing in the ears
- tremor, chills
- pallor
- blurred vision
- abnormal skin sensations like tingling

#### Local and general reactions:

- chest pain
- local skin reactions at the injection site: skin rash, itching, pain, swelling, inflammation and cellulitis (skin infection)

If you experience any of those, please refer immediately to your nuclear medicine doctor.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

#### Reporting of side effects

If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie);

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects, you can help provide more information on the safety of this medicine.

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### 5. HOW TECHNESCAN PYP IS STORED

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises.

Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

TechneScan PYP must not be used after the expiry date which is stated on the label after "EXP".

TechneScan PYP must not be used if there are visible signs of deterioration.

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## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What TechneScan PYP contains

The active substance is sodium pyrophosphate decahydrate.

One vial contains 20 mg sodium pyrophosphate decahydrate.

The other excipients are stannous chloride dihydrate, sodium hydroxide and hydrochloric acid.

### What TechneScan PYP looks like and contents of the pack

TechneScan PYP contains a powder, packed in a 10 ml type 1 glass vial with a bromobutyl stopper and closed with an aluminium cap.

Pack size: 5 vials.

### Marketing Authorisation Holder and Manufacturer

Curium Netherlands B.V.

Westerduinweg 3

1755 LE Petten

The Netherlands

This leaflet was last revised in {MM/YYYY}.

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The following information is intended for medical or healthcare professionals only:

The complete Summary of Product Characteristics (SmPC) of TechneScan PYP is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical. Please refer to the SmPC of TechneScan PYP.