SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TechneScan PYP 20 mg kit for radiopharmaceutical preparation

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 20 mg sodium pyrophosphate decahydrate and 4 mg stannous chloride dihydrate (corresponding to 2.1 mg stannous).
The radionuclide is not part of the kit.
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation.
Powder for solution for injection.
Off-white to slightly yellow lyophilizate.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

A. Red blood cell labelling for blood pool scintigraphy.
Major indications are:
- Angiocardioscintigraphy for:
  - evaluation of ventricular ejection fraction
  - evaluation of global and regional cardiac wall motion
  - myocardial phase imaging
- Organ perfusion and vascular abnormalities imaging for the detection of hemangioma.
- Diagnosis and localization of occult gastro-intestinal bleeding

B. Determination of blood volume

C. Spleen scintigraphy

4.2 Posology and method of administration

Posology

Adults

A. Blood pool scintigraphy:
The average activity administered after intravenous injection for *in vivo* or after *in vitro* labelling is 890 MBq (740-925 MBq).

B. Determination of blood volume:
The average activity administered after intravenous injection after *in vitro* labelling is 3 MBq (1-5 MBq).

C. Spleen scintigraphy:
The average activity administered after intravenous injection after *in vitro* labelling of denaturated erythrocytes is 50 MBq (20-70 MBq).

The optimal amount of nonradioactive stannous tin for preparation of red blood cells (RBCs) *in vivo* or *in vitro* is 10 to 20 µg/kg body weight in adults. Especially in cases of *in vitro* labelling this dose should not be exceeded. Sodium pertechnetate (^{99m}Tc) should be injected (*in vivo*) or added to the incubation mixture (*in vitro*) after 30 minutes.

Renal impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Paediatric population
The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group.
The activities to be administered to children and to adolescents may be calculated according to the EANM dosage card version 2016 for the indication:

Blood pool scintigraphy.
A[*MBq*]Administered = *56.0* x *Multiple from table 1*

Spleen scintigraphy:
A[*MBq*]Administered = 2.8 x *Multiple from table 1*

Table 1

3 kg = 1	22 kg = 5.29	42 kg = 9.14
4 kg = 1.14	24 kg = 5.71	44 kg = 9.57
6 kg = 1.71	26 kg = 6.14	46 kg = 10.00
8 kg = 2.14	28 kg = 6.43	48 kg = 10.29
10 kg = 2.71	30 kg = 6.86	50 kg = 10.71
12 kg = 3.14	32 kg = 7.29	52-54 kg = 11.29
14 kg = 3.57	34 kg = 7.72	56-58 kg = 12.00
16 kg = 4.00	36 kg = 8.00	60-62 kg = 12.71
18 kg = 4.43	38 kg = 8.43	64-66 kg = 13.43
20 kg = 4.86	40 kg = 8.86	68 kg = 14.00

For blood scintigraphy, in very young infants (up to 1 year) a minimum dose of 80 MBq is necessary in order to obtain images of sufficient quality. For spleen scintigraphy a minimum dose of 20 MBq is necessary.

Method of administration
Multidose vial.
For intravenous injection.

This medicinal product should be reconstituted before administration to the patient. For instructions regarding reconstitution, see section 12.
For patient preparation, see section 4.4.

The freeze-dried stannous pyrophosphate lyophilizate (non-radioactive substance) is first reconstituted with isotonic sodium chloride solution for injection.

In vivo RBCs labelling method:
Injection of the reconstituted solution of the stannous pyrophosphate complex followed by injection of sodium pertechnetate (^{99m}Tc) 30 minutes later.

In vitro RBCs labelling method:
- Sampling of 6 ml of the patient's blood
- *In vitro* incubation of the reconstituted solution of the taken total blood sample or separated RBCs, followed by adding sodium pertechnetate (^{99m}Tc) 30 minutes later.
- Second *in vitro* incubation of the RBCs and reinjection of the labelled RBCs 30 minutes later.

Modified in vivo RBCs labelling method (in vivo/in vitro):
- Injection of the reconstituted solution of the stannous pyrophosphate for *in vivo* "stannous-loading" of RBCs.
- *In vitro* RBCs labeling with sodium pertechnetate (^{99m}Tc) after taking a blood sample.
- Reinjection of the labelled RBCs.

Denatured RBCs labelling method:
- *In vitro* labelling of RBCs (see above) followed by denaturation e.g. heating of the labelled erythrocytes at 49-50°C for 25 minutes.
- Reinjection of the labelled denatured RBCs.

Image acquisition

Angiocardioscintigraphy:
The acquisition of images starts immediately after the injection of the tracer.

Occult digestive haemorrhages:
Since digestive bleeding occurs usually intermittently, it is recommended to perform several acquisitions over a period of 24 hours in addition to the images acquired initially after the injection.

Spleen scintigraphy:
Images are performed from 30 to 120 minutes after the injection. In case of accessory spleen research, the entire abdomen should be studied. If the patient has diaphragm rupture due to previous trauma, the chest should also be studied.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Potential for hypersensitivity or anaphylactic reactions
If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately, and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

Individual benefit/risk justification
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Renal impairment
Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

Paediatric population
For information on the use in paediatric population, see section 4.2. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults, see section 11.

After the procedure
Close contact with infants and pregnant women should be restricted during 2 hours after administration of the labelled RBCs or sodium pertechnetate (^{99m}Tc).

Specific warnings

Scintigraphy repeatability
Because of the long-lasting fixation of stannous salts on red blood cells, it is recommended not to repeat the procedure before 3 months.

Interaction with iodinated contrast media
It is recommended to perform the scintigraphy with (^{99m}Tc)-labelled red blood cells in advance of any administration of the iodinated contrast media, otherwise the efficiency of the red blood cell labelling will be adversely affected (see section 4.5).

Sodium content
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'. Depending on the time when you administer the injection, the content of sodium given to the patient may in some cases be greater than 1 mmol. This should be taken into account in patient on low sodium diet.

Precautions with respect to environmental hazard see section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction

Reduction in red blood cell labelling yield has been reported with heparin, tin overload, aluminium, prazosin, methyldopa, hydralazine, digitalic related compounds, quinidine, β-adrenergic blockers (e.g. propranolol), calcium channel blockers (e.g. verapamil, nifedipine), nitrates (e.g. nitroglycerine), anthracycline antibiotic, iodinated contrast agents and teflon catheter (the Sn^{++} can react with the catheter).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if a period is very irregular, etc), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy
Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.
Administration of 925 MBq results in an absorbed dose to the uterus of 3.6 mGy.

Breast-feeding
Before administering radiopharmaceuticals to a mother who is breast-feeding a consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast-feeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk.
Sodium pertechnetate (^{99m}Tc) is excreted in human milk. If the administration is considered necessary and depending on the RBCs labelling method, breastfeeding should at least be interrupted for about 12 hours after the sodium pertechnetate (^{99m}Tc) injection (*in vivo* labelling method) or for about 4 hours after the reinjection of the labelled RBCs (other labelling methods), and the expressed feeds discarded. Close contact with infants should be restricted during 2 hours (see section 4.4).

Fertility
There are no data on possible harmful effects of TechneScan PYP on fertility.

4.7 Effects on ability to drive and use machines

TechneScan PYP has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 6.5 mSv when the maximal recommended activity of 925 MBq is administered these adverse reactions are expected to occur with a low probability.

Information on adverse reactions is available from spontaneous reporting. The reports describe anaphylactoid, vasovagal and injection site reactions.

Adverse Reactions sorted by System Organ Class

Immune system disorders Frequency not known*	Anaphylactoid reaction [e.g. general skin pruritus, vasodilation, urticaria, erythema, diaphoresis, facial oedema, swollen arm, nausea, vomiting, flushing, cardiac arrhythmias (tachycardia), hypotension, hyperhidrosis, coma, dyspnoea, dysphagia, muscle spasms, lacrimation increased, myalgia, taste disorder].
Nervous system disorders Frequency not known*	Vasovagal reaction (e.g. syncope, headache, dizziness, confusional state, bradycardia, tinnitus, tremor, chills, pallor, blurred vision, paraesthesia).
General disorders and administration site conditions Frequency not known*	Chest pain. Injection site reactions (e.g. skin rash, pruritus, cellulitis, inflammation, pain, swelling)

* Frequency cannot be estimated from the available data.

Anaphylactoid reactions
Reported anaphylactoid reactions were mild to moderate, however the occurrence of severe reactions cannot be excluded. If anaphylactoid reactions occur, the medicinal product must no longer be administered. Appropriate instruments (including endotracheal tube and ventilator) and medications should be to hand to be able to react immediately in an emergency.

Vasovagal reactions
Vasovagal reactions are most probably caused by the procedure itself, especially in anxious patients, but a contribution of the product cannot be excluded.

Injection site reactions
Local reactions at the injection site may include rashes, pruritus, cellulitis, swelling, inflammation and pain. In most cases such reactions are probably caused by extravasation. Extended extravasation may necessitate surgical treatment.

Paediatric population
It must be taken into account that the effective dose per MBq is higher than in adults (see section 11. "Dosimetry").

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

In the event of an administered radiation overdose on TechneScan PYP, very little can be done since the elimination of it completely depends of the regular hemolytic process.
Forced diuresis and frequent bladder voiding are recommended in the case of overdosage with sodium pertechnetate (^{99m}Tc).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Diagnostic radiopharmaceuticals for cardiovascular system, Technetium (^{99m}Tc) compounds.
ATC code: V09GA06.

At doses used for diagnostic procedures, neither stannous pyrophosphate, sodium pertechnetate (^{99m}Tc) nor stannous pyrophosphate (^{99m}Tc), nor labelled Red Blood Cells appear to have any pharmacodynamic effect.

5.2 Pharmacokinetic properties
Distribution
Intravenous injection of stannous salts induces a “stannous loading” of erythrocytes. Subsequent sodium pertechnetate (^{99m}Tc) injection results in an accumulation and a retention of sodium pertechnetate (^{99m}Tc) in the choroid plexus and red blood cells.
Intravenous administration of 10-20 µg stannous ion/kg body weight (in form of stannous pyrophosphate) followed 30 minutes later by 370-740 MBq pertechnetate injection results in efficient labelling of blood pool.

Organ uptake
Under normal circumstances intravenously injected pertechnetate freely diffuses into and out from the erythrocytes. However, when the erythrocytes have been preloaded with stannous ion, the sodium pertechnetate (^{99m}Tc) is reduced within the cells and becomes bound to the chains of globin. The mechanisms by which sodium pertechnetate (^{99m}Tc) becomes attached to tin primed red blood cells are not clearly understood. However, 20 % of injected pertechnetate enters the red cell and binds to a beta chain of globin, while the remaining 70-80 % of pertechnetate is believed to be located in the cytoplasm or on the red cell membrane. On the other hand, reducing the surface charge of the erythrocytes decreases the efficiency of labelling down to 20 %.

Elimination
The most beneficial time for the injection of (^{99m}Tc) pertechnetate for the *in vivo* labelling is 20-30 min after the administration of pyrophosphate. At 10 and 100 minutes post injection, 77 ± 15 % and 71 ± 14 % respectively, of the injected activity is found in the blood. This value remains constant for about 2 hours after injection with only about 6 % decrease in total blood radioactivity during this period.

Half-life
Up to eight days after the examination, labelling of erythrocytes with (^{99m}Tc) pertechnetate may still be observed. There is no appreciable effect with doses of up to 0.02 mg of tin/kg. The heat-denatured erythrocytes are sequestrated by splenic pulp.
Technetium-99m (^{99m}Tc) has a physical half-life of 6 hours.

5.3 Preclinical safety data
There are no preclinical safety data specific to technetium labelled erythrocytes. The toxicity of pertechnetate ion and stannous salts has been studied and reported in the literature. Systemic toxic effects are only observed at relatively high parenteral doses, giving a safety ratio of at least 150. Repeated dose toxicity studies in rats with 50-100 times human dose do not cause macroscopic nor microscopic alterations. Stannous salts are reported to have a weak potential for mutagenicity. There are no studies describing possible effects on reproduction or tumour incidence.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Stannous chloride dihydrate
Hydrochloric acid
Sodium hydroxide (for pH-adjustment)

6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section 12.

6.3 Shelf life
1 year.
After reconstitution: 4 hours.
After reconstitution, store in a refrigerator (2-8 °C).
From microbiological point of view the product should be used immediately.

6.4 Special precautions for storage
Store in a refrigerator (2-8 °C).
For storage conditions after reconstitution of the medicinal product, see section 6.3.
Storage should be in accordance with national regulations for radioactive material.

6.5 Nature and contents of container
10 ml glass vial (type 1 Ph.Eur.) closed with a bromobutyl stopper, sealed with an aluminium cap.
Pack size: five vials in a carton.

6.6 Special precautions for disposal and other handling
General warnings
Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the local competent authorities.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiological safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Contents of the vial are intended only for use in the preparation of radiopharmaceuticals and are not to be administered directly to the patient without first undergoing the reconstitution procedure.

For instructions on reconstitution of the medicinal product before administration, see section 12.

If at any time in the preparation of this product the integrity of this vial is compromised, it should not be used.

Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

The content of the kit is not radioactive. However, after sodium pertechnetate (^{99m}Tc) is added to the RBCs during *in vitro* RBC labelling, adequate shielding of the final preparation must be maintained.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

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

7. PRODUCT OWNER
Manufactured and released by:
Curium Netherlands B.V.
Westerduinweg 3
1755 LE PETTEN
The Netherlands

Marketing Authorisation Holder:
QT Instruments (S) Pte Ltd
100H Pasir Panjang Road
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8. MARKETING AUTHORISATION NUMBER(S)
SIN16274P

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
09.07.2021

10. DATE OF REVISION OF THE TEXT
08.05.2023

11. DOSIMETRY
Technetium (^{99m}Tc) is produced by means of a (^{99}Mo/^{99m}Tc) generator and decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6.02 hours to technetium (^{99m}Tc) which, in view of its long half-life of 2.13×10^5 years can be regarded as quasi stable.

The radiation doses absorbed by a patient with a body weight of 70 kg after intravenous injection of ^{99m}Tc-labelled erythrocytes according to ICRP 128 (2015) and ^{99m}Tc-labelled denatured erythrocytes according to ICRP 53 (1988), are as following.

^{99m}Tc-LABELLED ERYTHROCYTES

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 Years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0099	0.012	0.02	0.03	0.056
Bone Surfaces	0.0074	0.012	0.019	0.036	0.074
Brain	0.0036	0.0046	0.0075	0.012	0.022
Breast	0.0035	0.0041	0.007	0.011	0.019
Gall bladder wall	0.0065	0.0081	0.013	0.02	0.03
GI-tract					
Stomach wall	0.0046	0.0059	0.0097	0.014	0.025
Small Intestine wall	0.0039	0.0049	0.0078	0.012	0.021
Colon wall	0.0037	0.0048	0.0075	0.012	0.02
ULI wall	0.004	0.0051	0.008	0.013	0.022
LLI wall	0.0034	0.0044	0.0069	0.01	0.018
Heart wall	0.023	0.029	0.043	0.066	0.11
Kidneys	0.018	0.022	0.036	0.057	0.11
Liver	0.013	0.017	0.026	0.04	0.072
Lungs	0.018	0.022	0.035	0.056	0.11
Muscles	0.0033	0.004	0.0061	0.0094	0.017
Oesophagus	0.0061	0.007	0.0098	0.015	0.023
Ovaries	0.0037	0.0048	0.007	0.011	0.019
Pancreas	0.0066	0.0081	0.013	0.019	0.033
Red marrow	0.0061	0.0076	0.012	0.02	0.037
Skin	0.002	0.0024	0.0038	0.0062	0.012
Spleen	0.014	0.017	0.027	0.043	0.081
Testes	0.0023	0.003	0.0044	0.0069	0.013
Thymus	0.0061	0.007	0.0098	0.015	0.023
Thyroid	0.0057	0.0071	0.012	0.019	0.036
Urinary bladder wall	0.0085	0.011	0.014	0.017	0.031
Uterus	0.0039	0.0049	0.0074	0.011	0.019
Remaining organs	0.0035	0.0045	0.0073	0.013	0.023
Effective dose (mSv/MBq)	**0.007**	**0.0089**	**0.014**	**0.021**	**0.039**

For blood pool scintigraphy the effective dose resulting from the administration of a (maximum recommended) activity of 925 MBq is 6.5 mSv (for an adult weighing 70 kg) and the typical radiation dose to the critical organ (heart) is 21.3 mGy.

For blood volume determination the effective dose resulting from the administration of a (maximal recommended) activity of 5 MBq is 0.035 mSv (for an adult weighing 70 kg) and the typical radiation dose to the critical organ (heart) is 0.12 mGy.

^{99m}Tc-LABELLED DENATURED ERYTHROCYTES

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 Years**	**10 years**	**5 years**	**1 year**
Adrenals	0.013	0.018	0.027	0.038	0.063
Bladder wall	0.00075	0.0011	0.0021	0.0038	0.0073
Bone Surfaces	0.0031	0.0041	0.0061	0.0095	0.019
Breast	0.0021	0.0021	0.0041	0.0068	0.010
GI-tract					
Stomach wall	0.019	0.021	0.030	0.040	0.058
Small intestine	0.0037	0.0046	0.0077	0.013	0.022
ULI wall	0.0040	0.0049	0.0085	0.014	0.023
LLI wall	0.0017	0.0023	0.0043	0.0069	0.013
Heart	0.0060	0.0073	0.011	0.016	0.026
Kidneys	0.018	0.022	0.032	0.046	0.070
Liver	0.018	0.023	0.034	0.049	0.087
Lungs	0.0057	0.0075	0.011	0.017	0.028
Ovaries	0.0014	0.0022	0.0039	0.0070	0.012
Pancreas	0.036	0.040	0.057	0.078	0.12
Red marrow	0.0043	0.0060	0.0084	0.011	0.017
Spleen	0.56	0.78	1.2	1.8	3.2
Testes	0.00047	0.00059	0.0011	0.0017	0.0041
Thyroid	0.00063	0.0010	0.0018	0.0032	0.0066
Uterus	0.0014	0.0018	0.0036	0.0059	0.011
Other tissue	0.0033	0.0041	0.0058	0.0087	0.015
Effective dose * (mSv/MBq)	**0.019**	**0.026**	**0.04**	**0.06**	**0.1**

* Calculation according to ICRP 60

For spleen scintigraphy the effective dose resulting from the administration of a (maximum recommended) activity of 70 MBq is 1.3 mSv (for an adult weighing 70 kg) and the typical radiation dose to the critical organ (spleen) is 39.2 mGy.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Withdrawals should be performed under aseptic conditions. The vials must never be opened before disinfecting the stopper, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorised automated application system.
If the integrity of this vial is compromised, the product should not be used.

The freeze-dried stannous pyrophosphate lyophilizate (non-radioactive substance) is first reconstituted with isotonic sodium chloride solution. TechneScan PYP is a colourless solution after reconstitution. Reconstituted solution is then used for *in vivo*, *in vitro* or *in vivo/in vitro* labelling of red blood cells by different methods.

In vivo RBCs labelling

Blood pool scintigraphy:

- In the case of ca. 70 kg body weight: slowly inject (10-20 seconds) 1/3 of the whole contents of one vial TechneScan PYP dissolved in 6 ml of an isotonic sodium chloride solution (2 ml for 70 kg). The volume should be adapted for other body weights.
- Inject approximately 30 minutes later 740-925 MBq pertechnetate (^{99m}Tc) intravenously

In vitro RBCs labelling

- Collect 6 ml blood from the patient in ACD (acid citrate dextrose)
- Remove plasma by centrifugation and perform a wash step with isotonic sodium chloride
- Resuspend the erythrocytes in ca 10 ml isotonic sodium chloride solution
- Dissolve a vial TechneScan PYP in 6 ml isotonic sodium chloride solution
- Add 0.3 ml (105 µg Sn) reconstituted solution to the erythrocyte suspension
- Incubate for 30 minutes at room temperature
- Remove excess Sn^{2+} by centrifugation and by resuspension of the cells in 5 ml sodium chloride
- Repeat this wash step
- Add 740-925 MBq $^{99m}TcO_4^-$
- Incubate 30 minutes at room temperature
- Remove unbound ^{99m}Tc by centrifugation
- Determine the labelling yield; this should be >85%
- Reinject the labelled RBCs in the patient.

In vivo/in vitro RBCs labelling

- TechneScan PYP is reconstituted with 6 ml sterile, non-pyrogenic isotonic sodium chloride solution. One third of the vial is administered to the patient.
- 30 minutes later, collect 6 ml blood from the patient in ACD tubes. Add sodium pertechnetate (^{99m}Tc) and incubate 30 minutes at room temperature.
- Remove plasma and unbound pertechnetate by centrifugation and perform a wash step with 5 ml isotonic sodium chloride.
- Repeat this centrifugation and wash step.
- Reinject the labelled RBCs in the patient.

Denatured RBCs labelling method

- *In vitro* labelling of RBCs (see above) followed by denaturation e.g. heating of the labelled erythrocytes at 49-50°C for 25 minutes
- Reinject the labelled denatured RBCs in the patient.

Package leaflet: Information for the patient

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

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 a radioactive solution of sodium pertechnetate (^{99m}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}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.

2. What you need to know before TechneScan 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 substance 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’.

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 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 and sodium pertechnetate (^{99m}Tc) to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity of sodium pertechnetate (^{99m}Tc) 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 (^{99m}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 (^{99m}Tc) solution. Your radiolabelled red blood cells are then reinjected into a vein. One injection of TecheScan 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.

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
- low 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 or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

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.

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 I glass vial with a bromobutyl stopper and closed with an aluminium cap. Pack size: 5 vials.

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This leaflet was last revised in May 2023.

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.

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