SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PoltechRBC, 13.40 mg, lyophilisate for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains:
Active ingredients: sodium pyrophosphate decahydrate 13.40 mg
Excipient: stannous (II) chloride dihydrate 4.3 mg
The radionuclide is not part of the kit.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for solution for injection.
White powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

This medicinal product is indicated for:

- *In vivo*, *in vitro* or *in vivo/in vitro* red blood cell labelling for blood pool scintigraphy used for:
  - angiocardioscintigraphy for:
  - evaluation of ventricular ejection fraction,
  - evaluation of global and regional cardiac wall motion,
  - phase analysis of myocardial contractility.
  - organ perfusion and vascular abnormalities imaging.
  - diagnosis and localization of occult gastrointestinal bleeding.

- Determination of blood volume.

- Spleen scintigraphy.

4.2 Posology and method of administration

This medicinal product is for intravenous injection.
Before administration to the patient, this medicinal product should be reconstituted with isotonic sodium chloride solution for injection.
For instruction on reconstitution of the product before administration, see section 12.
For patient preparation, see section 4.4.

For diagnostic scintigraphy based on labelled erythrocytes, complex of pyrophosphate with tin (II) is prepared by dissolving lyophilisate in normal saline.

Red blood cells labelling methods

In vivo method

Inject appropriate volume of solution prepared by dissolving contents of the vial in normal saline, and then administer intravenously sterile solution of sodium ^{99m}Tc-pertechnetate (eluate from ^{99}Mo/^{99m}Tc generator).

In vitro method

Collect a sample of blood from the patient. Incubate *in vitro* the blood sample or isolated erythrocytes with appropriate volume of solution prepared by dissolving contents of the vial in normal saline, add sterile solution of sodium ^{99m}Tc-pertechnetate and inject labelled erythrocytes into the patient.

In vivo/in vitro method

Inject intravenously appropriate volume of solution prepared by dissolving contents of the vial in normal saline in order to introduce stannous ions into erythrocytes *in vivo*. Subsequently collect a sample of blood from the patient and label *in vitro* with sodium ^{99m}Tc-pertechnetate. Inject labelled erythrocytes into the patient.

Labelling of denatured erythrocytes

Label erythrocytes *in vitro*, then denature them e.g. by heating at 49–50°C for 25 minutes. Inject labelled, denatured erythrocytes into the patient.

Posology

Blood pool scintigraphy

The average activity of ^{99m}Tc administered in single injection after *in vitro, in vivo/in vitro* or *in vitro* labelling is 800 MBq (500 – 1050 MBq).

Determination of blood volume

The average activity of ^{99m}Tc administered in single injection after *in vitro* labelling is 3 MBq (1-5 MBq).

Spleen scintigraphy

The average activity administered in single injection after *in vitro* labelling of denatured erythrocytes is 50 MBq (20-70 MBq).

In light of the European Directive 97/43/Euratom and current practice throughout Europe, the above activities should be considered only as a general indication. It should be noted that in each country nuclear medicine physicians should respect the diagnostic reference levels (DRL) and the rules laid down by the local legislation. The injection of activities greater than local DRLs should be justified.

Paediatric population

The use of the medicinal product in paediatric patients has to be considered carefully, based upon clinical needs and assessment of the risk/benefit ratio in this patient group. The activity for children may be calculated by modifying the adult activity according to body weight or body surface of the child. According to recommendations of The Paediatric Task Group of the European Association of Nuclear Medicine (EANM) the paediatric dose is a part of adult dose and is calculated based on the body weight of the child according to the following table.

Body weight of the child	Dose (part of adult dose)	Body weight of the child	Dose (part of adult dose)
3 kg	0.1	32 kg	0.65
4 kg	0.14	34 kg	0.68
6 kg	0.19	36 kg	0.71
8 kg	0.23	38 kg	0.73
10 kg	0.27	40 kg	0.76
12 kg	0.32	42 kg	0.78
14 kg	0.36	44 kg	0.80
16 kg	0.40	46 kg	0.82
18 kg	0.44	48 kg	0.85
20 kg	0.46	50 kg	0.88

22 kg	0.50	52 – 54 kg	0.90
24 kg	0.53	56 – 58 kg	0.92
26 kg	0.56	60 – 62 kg	0.96
28 kg	0.58	64 – 66 kg	0.98
30 kg	0.62	68 kg	0.99

For diagnostics studies in infants performed with labelled erythrocytes minimum activity necessary to obtain images of sufficient quality is 80 MBq. Minimum activity required for spleen scintigraphy is 20 MBq. It is recommended not to repeat the procedure within 3 months due to long-lasting retention of stannous salts in erythrocytes.

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

For each patient, the radiation exposure must be justifiable by the expected benefits resulting from diagnostic procedure using the radiopharmaceutical. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Pregnancy, see section 4.6.

Children and adolescents, see section 4.2.

It is recommended to label erythrocytes with ^{99m}Tc by *in vivo* method prior to possible administration of iodinated contrast media. Otherwise, labelling efficiency will be reduced.

The patient should be well hydrated before the start of the examination in order to reduce radiation exposure of urinary bladder. In case of renal failure radiation exposure can increase. It should be taken into account to calculate administered activity of the radiopharmaceutical.

4.5 Interactions with other medicinal products and other forms of interactions

Reduction in erythrocytes labelling efficiency has been reported in the presence of heparine, prazosin, methyldopa, hydralazine, digitalis glycosides, quinidine, adrenergic β-receptor inhibitors, calcium channel inhibitors (e.g. verapamil, nifedipine), nitrates (e.g. nitroglicerin), anthracycline antineoplastic drugs, iodinated contrast media, after injection through teflon cannulas (Sn(II) can react with the cannula material) and in the increased concentrations of tin and aluminium.
Administration of pyrophospate-tin(II) complex and sodium ^{99m}Tc-pertechnetate solution through the same intravenous route should be avoided.

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 the period is very irregular, etc.), alternative diagnostic 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 the foetus.

The dose absorbed by the uterus after administration of erythrocytes labelled with 800 MBq ^{99m}Tc is 4.6 mGy. Radiation doses exceeding 0.5 mGy should be regarded as potentially dangerous for the foetus.

Breastfeeding
Before administration of the radiopharmaceutical to a mother who is breastfeeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding and as to whether the most appropriate choice of radiopharmaceuticals has been made.
If the administration of the radiopharmaceutical is considered necessary, in case of erythrocytes labelled by *in vivo* or *in vivo/in vitro* method, breastfeeding should be interrupted for 12 hours. If the erythrocytes were labelled by *in vitro* method, it is not necessary to cease breastfeeding, however the first portion of milk obtained after administration of the radiopharmaceutical should be discarded. It is usual to advise that breastfeeding can be restarted when the radioactivity level in the milk will not result in a radiation dose to the child greater than 1 mSv.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

For each patient, exposure to ionising radiation must be justified on the basis of likely benefit resulting from the study. The activity administered must be such that the resulting radiation dose absorbed by the patient is as low as reasonably achievable bearing in mind the need to obtain the required diagnostic information.
Adverse reactions after intravenous administration of both labelled with ^{99m}Tc and unlabelled complexes were observed in very rare cases (1 – 5 per 100000 injections).
The frequency of adverse reactions reported after administration of the medicinal product is presented in the table below.

Cardiac disorders Arrhythmia	Frequency not known (cannot be estimated from the available data)
Congenital, familial and genetic disorders Hereditary defects	Frequency not known (cannot be estimated from the available data)
Nervous system disorders Headache, dizziness, vasovagal reactions	Frequency not known (cannot be estimated from the available data)
Gastrointestinal disorders Nausea, vomiting	Frequency not known (cannot be estimated from the available data)
Skin and subcutaneous tissue disorders Skin rashes	Frequency not known (cannot be estimated from the available data)
Neoplasms benign, malignant and unspecified (including cysts and polyps) Cancer induction	Frequency not known (cannot be estimated from the available data)
Vascular disorders Hypotension, flushing	Frequency not known (cannot be estimated from the available data)
General disorders and administration site conditions Facial oedema, injection site reactions	Frequency not known (cannot be estimated from the available data)
Immune system disorders Allergic reactions	Frequency not known (cannot be estimated from the available data)

Exposure to ionising radiation is linked with cancer induction risk and a potential for development of hereditary defects. The current evidence suggests that for diagnostic nuclear medicine studies these adverse effects are expected to occur with low probability.

The radiation dose (effective dose) for most diagnostic nuclear medicine investigations is less than 20 mSv. Higher doses may be justified in some clinical circumstances.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

In the event of the accidental administration of an overdose of the radiopharmaceutical very little supportive treatment can be undertaken since its elimination is entirely dependent on the normal haemolytic process. Forced diuresis and frequent bladder emptying are recommended in the case of overdosage of sodium ^{99m}Tc-pertechnetate.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: diagnostic radiopharmaceuticals, cardiovascular system, technetium compounds (^{99m}Tc), ATC code: V 09G A06.

At doses used for diagnostic studies, neither complex of pyrophosphate with tin (II), nor sodium ^{99m}Tc-pertechnetate, nor technetium – 99m labelled red blood cells appear to exert any pharmacodynamic effect.

5.2 Pharmacokinetic properties

Intravenous administration of stannous salts results in their permanent binding to erythrocytes. Subsequent intravenous injection of sodium ^{99m}Tc-pertechnetate induces accumulation and retention of ^{99m}Tc in erythrocytes and choroid plexus.
Intravenous administration 10 - 20 µg stannous ions/kg body weight (in the form of complex of pyrophosphate with tin (II)) with subsequent sodium ^{99m}Tc-pertechnetate injection 30 minutes later results in efficient labelling of blood pool.
Under normal circumstances sodium ^{99m}Tc-pertechnetate freely diffuses through erythrocytic cell membranes. However, in the presence of stannous ions in erythrocytes, ^{99m}Tc-pertechnetate ions are reduced and bind with the β-chains of haemoglobin. The mechanism of binding is not clearly understood. About 20% of administered ^{99m}Tc is bound to the β-chains of haemoglobin. It is believed, that the remaining 70% – 80% of ^{99m}Tc remains in the cytoplasm and cell membrane of erythrocytes.
The most beneficial time of injection of ^{99m}Tc for the *in vivo* labelling ranges from 20 to 30 minutes after administration of pyrophosphate - tin (II) complex.
Ten and one hundred minutes post injection 77% ± 15% and 71% ± 14% of activity, respectively, is found in the blood. This value remains constant for 2 hours (only small, about 6 % decrease is observed).
Erythrocytes labelled with technetium-99m are found in the circulation up to 8 days after the study. Tin, at a dose up to 20 µg/kg body weight, does not exert any noticeable untoward effect. Heat denatured erythrocytes undergo sequestration in the spleen pulp.

5.3 Preclinical safety data

There are no preclinical safety data specific to technetium labelled erythrocytes. Reports are available only regarding toxicity of pertechnetate ion and stannous salts. Systemic toxic effects were observed only

after parenteral administration of relatively high doses, what results in high therapeutic index of at least 150.
In rats, repeated dose toxicity studies with 50-100 times human doses, did not cause macroscopic or microscopic alterations. Weak mutagenic properties of stannous salts were reported. There are no studies describing possible effects on reproduction or tumour induction risk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stannous chloride dihydrate 4.3 mg
Nitrogen

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the kit is 1 year.
After reconstitution with normal saline, the product should be used within 3 hours, if stored below 25°C.

6.4 Special precautions for storage

Store in a refrigerator (2°C- 8°C).
During transportation (no longer than 7 days) up to 35°C is permitted.
For storage conditions after reconstitution of the medicinal product, see section 6.3.
Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

6.5 Nature and contents of container

10 ml glass vial, sealed with rubber stopper and an aluminium crimp cap. Vials are packed in cardboard boxes. Pack sizes of 3 or 6 vials are available. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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 licences of the competent official organisation.
Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.
Contents of the vial are intended only for use in the preparation of radiopharmaceutical and are not to be administered directly to the patient without first undergoing the preparative procedure.
The content of the kit before extemporary preparation is not radioactive. However, after sodium ^{99m}Tc-pertechnetate solution is added, adequate shielding of the final preparation must be maintained.
The administration of radiopharmaceuticals creates risk for other persons from external radiation or contamination from spills of urine, vomits, 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.

Instruction for preparation of the radiopharmaceutical - see section 12.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

R/3441

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 24.02.1979
Date of latest renewal: 05.02.2013

10. DATE OF REVISION OF THE TEXT

22.09.2015

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 141 keV and a half-life of 6.02 hours to technetium ^{99}Tc, which, in view of its long half-life of 2.13 x 10^5 years, can be regarded as quasi-stable.
The radiation doses absorbed by a patient weighing 70 kg, after intravenous administration of ^{99m}Tc labelled erythrocytes and denatured ^{99m}Tc labelled erythrocytes are reported below. Data were obtained from ICRP Publication (*International Commision on Radiological Protection, Radiation Dose to Patients from Radiopharmaceuticals*).

Technetium ^{99m}Tc labelled erythrocytes: Absorbed dose per unit activity administered [mGy/MBq]					
Organ	Adults	15 years	10 years	5 years	1 year
Adrenals	9.9E-03	1.2E-02	2.0E-02	3.0E-02	5.6E-02
Bladder wall	8.5E-03	1.1E-02	1.4E-02	1.7E-02	3.1E-02
Bone surfaces	7.4E-03	1.2E-02	1.9E-02	3.6E-02	7.4E-02
Brain	3.6E-03	4.6E-03	7.5E-03	1.2E-02	2.2E-02
Breast	3.5E-03	4.1E-03	7.0E-03	1.1E-02	1.9E-02
Gall	6.5E-03	8.1E-03	1.3E-02	2.0E-02	3.0E-02
Gastrointestinal tract:					
Stomach wall	4.6E-03	5.9E-03	9.7E-03	1.4E-02	2.5E-02
Small intestine	3.9E-03	4.9E-03	7.8E-03	1.2E-02	2.1E-02
Colon	3.7E-03	4.8E-03	7.5E-03	1.2E-02	2.0E-02
(ULI)	4.0E-03	5.1E-03	8.0E-03	1.3E-02	2.2E-02
(LLI)	3.4E-03	4.4E-03	6.9E-03	1.0E-02	1.8E-02
Heart	2.3E-02	2.9E-02	4.3E-02	6.6E-02	1.1E-01
Kidneys	1.8E-02	2.2E-02	3.6E-02	5.7E-02	1.1E-01
Liver	1.3E-02	1.7E-02	2.6E-02	4.0E-02	7.2E-02
Lungs	1.8E-02	2.2E-02	3.5E-02	5.6E-02	1.1E-01
Muscles	3.3E-03	4.0E-03	6.1E-03	9.4E-03	1.7E-02
Oesophagus	6.1E-03	7.0E-03	9.8E-03	1.5E-02	2.3E-02
Ovaries	3.7E-03	4.8E-03	7.0E-03	1.1E-02	1.9E-02

Pancreas	6.6E-03	8.1E-03	1.3E-02	1.9E-02	3.3E-02
Red marrow	6.1E-03	7.6E-03	1.2E-02	2.0E-02	3.7E-02
Skin	2.0E-03	2.4E-03	3.8E-03	6.2E-03	1.2E-02
Spleen	1.4E-02	1.7E-02	2.7E-02	4.3E-02	8.1E-02
Testes	2.3E-03	3.0E-03	4.4E-03	6.9E-03	1.3E-02
Thymus	6.1E-03	7.0E-03	9.8E-03	1.5E-02	2.3E-02
Thyroid	5.7E-03	7.1E-03	1.2E-02	1.9E-02	3.6E-02
Uterus	3.9E-03	4.9E-03	7.4E-03	1.1E-02	1.9E-02
Remaining organs	3.5E-03	4.5E-03	7.3E-03	1.3E-02	2.3E-02
Effective dose (mSv/MBq)	**7.0E-03**	**8.9E-03**	**1.4E-02**	**2.1E-02**	**3.9E-02**

For blood pool scintigraphy the effective dose resulting from administration of 800 MBq to a patient of 70 kg body weight is 5.6 mSv, and the dose to critical organ (heart) is 18 mGy.

For blood volume determination the effective dose resulting from administration of 5 MBq to a patient of 70 kg body weight is 0.035 mSv.

Technetium ^{99m}Tc labelled denatured erythrocytes: Absorbed dose per unit activity administered [mGy/MBq]					
Organ	Adults	**15 year**	**10 year**	**5 year**	**1 year**
Adrenals	1.3E-02	1.8E-02	2.7E-02	3.8E-02	6.3E-02
Bladder wall	7.5E-04	1.1E-03	2.1E-03	3.8E-03	7.3E-03
Bone surfaces	3.1E-03	4.1E-03	6.1E-03	9.5E-03	1.9E-02
Breast	2.1E-03	2.1E-03	4.1E-03	6.8E-03	1.0E-02
Gastrointestinal tract: Stomach wall	1.9E-02	2.1E-02	3.0E-02	4.0E-02	5.8E-02
Small intestine	3.7E-03	4.6E-03	7.7E-03	1.3E-02	2.2E-02
(ULI)	4.0E-03	4.9E-03	8.5E-03	1.4E-02	2.3E-02
(LLI)	1.7E-03	2.3E-03	4.3E-03	6.9E-03	1.3E-02
Heart	6.0E-03	7.3E-03	1.1E-02	1.6E-02	2.6E-02
Kidneys	1.8E-02	2.2E-02	3.2E-02	4.6E-02	7.0E-02
Liver	1.8E-02	2.3E-02	3.4E-02	4.9E-02	8.7E-02
Lungs	5.7E-03	7.5E-03	1.1E-02	1.7E-02	2.8E-02
Ovaries	1.4E-03	2.2E-03	3.9E-03	7.0E-03	1.2E-02
Pancreas	3.6E-02	4.0E-02	5.7E-02	7.8E-02	1.2E-01
Red marrow	4.3E-03	6.0E-03	8.4E-03	1.1E-02	1.7E-02
Spleen	5.6E-01	7.8E-01	1.2E+00	1.8E+00	3.2E+00
Testes	4.7E-04	5.9E-04	1.1E-03	1.7E-03	4.1E-03
Thyroid	6.3E-04	1.0E-03	1.8E-03	3.2E-03	6.6E-03
Uterus	1.4E-03	1.8E-03	3.6E-03	5.9E-03	1.1E-02
Remaining organs	3.3E-03	4.1E-03	5.8E-03	8.7E-03	1.5E-02
Effective dose (mSv/MBq)	**4.1E-02**	**5.6E-02**	**8.4E-02**	**1.3E-01**	**2.2E-01**

For spleen scintigraphy the effective dose resulting from administration of 70 MBq to a patient of 70 kg body weight is 2.9 mSv, and the dose to critical organ (spleen) is 39 mGy.

12. INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and

pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Like in case of all pharmaceutical products, if the integrity of the vial is compromised during preparation, the product should not be used. Prior to labelling inspect the vial carefully for the presence of damage, particularly cracks.

Preparation of the solution for erythrocytes labelling

- Inject with a syringe (piercing the rubber stopper) 5 mL of normal saline into a vial containing lyophilisate.
- Without withdrawing the needle and using the same syringe, remove an equal volume of headspace to equilibrate the pressures.
- Shake the contents of the vial until complete dissolution (about 2 minutes).

The obtained solution is ready to use solution for erythrocytes labelling. 1 mL of this solution for erythrocytes labelling contains 0.45 mg Sn(II).

In vivo labelling of erythrocytes

- Slowly (during about 10 – 20 s) inject intravenously the volume of the solution for erythrocytes labelling containing 10 – 20 µg Sn(II)/kg patient body weight (for 70 kg patient the recommended volume is 1.55-3.1 mL). Injected volume should be modified according to the body weight of the patient.
- After about 30 min. inject intravenously 800 MBq (500 – 1050 MBq) sodium ^{99m}Tc-pertechnetate (eluate from ^{99}Mo/^{99m}Tc generator).

In vivo/in vitro labelling of erythrocytes

- Slowly (during about 10 – 20 s) inject intravenously the volume of the solution for erythrocytes labelling containing 10 – 20 µg Sn(II)/kg patient body weight (for 70 kg patient the recommended volume is 1.55-3.1 ml). Injected volume should be modified according to the body weight of the patient. .
- After about 15 – 30 minutes collect a sample (3 – 10 mL) of blood in syringe containing anticoagulant (ACD or heparine) and 800 MBq (500 – 1050 MBq) sodium ^{99m}Tc-pertechnetate.
- Mix the blood with sodium ^{99m}Tc-pertechnetate and incubate 10 – 20 minutes at room temperature, mixing occasionally.
- Unbound ^{99m}Tc (in the form of ^{99m}Tc-pertechnetate) can be removed by centrifugation and subsequently, after suspending separated erythrocytes in normal saline injected into the patient. Purification of labelled erythrocytes can be omitted if labelling efficiency complies with the requirements.

In vitro labelling of erythrocytes

- Collect 6 mL blood from the patient into tube containing heparin or ACD.
- Centrifuge erythrocytes and remove plasma.
- Wash the erythrocytes with normal saline and centrifuge.
- Suspend erythrocytes in about 10 mL of normal saline.
- To the erythrocyte suspension add from 1 to 50 µg Sn^{2+} in solution prepared by dilution of 1 mL of the solution for erythrocytes labelling with normal saline.
- Incubate for 30 minutes at room temperature.
- Remove excess solution of pyrophosphate-tin (II) complex by centrifugation and resuspend erythrocytes in 5 mL of normal saline.
- Repeat erythrocytes wash step as described above.
- Add adequate activity of sodium ^{99m}Tc-pertechnetate.
- Incubate for 30 minutes at room temperature. Remove free ^{99m}Tc by centrifugation of erythrocytes.
- Suspend erythrocytes in normal saline and inject into a patient.

Prior to injection determine erythrocytes labelling efficiency as described below.
Product can be administered to a patient if labelling efficiency ≥ 85%.

Method of determination of efficiency of erythrocytes labelling with ^{99m}Tc:

Take 0.2 mL of suspension of labelled erythrocytes.
Add 2 mL 0.9% NaCl; mix gently.
Centrifugate 5 minutes, remove plasma by pipetting.
Determine activity of plasma and erythrocytes.

$$\% \text{ efficiency of erythrocytes labelling} = \frac{\text{count number erythrocytes} \times 100\%}{\text{count number erythrocytes} + \text{count number plasma}}$$

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