MEDI-RADIOPHARMA

Your Global Nuclear Medicine Supplier

CATALOGUE OF IN VIVO KITS FOR ^{99m}Tc LABELLING

MRP
MEDI-RADIOPHARMA
Your Global Nuclear Medicine Supplier

INTRODUCTION

MEDI-RADIOPHARMA Ltd. is a privately-owned company established in 1995, with over 29 years of expertise in developing, manufacturing, and supplying radiopharmaceutical products globally.

Specializing in the production of cold kits for labeling ^{99m}Tc used in nuclear medicine diagnostics, MEDI-RADIOPHARMA Ltd. offers a diverse portfolio of products registered in numerous countries worldwide, including EU member states and Taiwan.
We pride ourselves on delivering a consistent supply of diagnostic solutions, ensuring the highest standards of quality and safety at every production stage.

Our certifications include:

- Manufacturer's Authorization
- Certificate of GMP Compliance of a Manufacturer
- Wholesale Distribution Authorization
- Certificate of GDP Compliance of a Wholesale Distributor
- Good Laboratory Practice (GLP) Certificate
- ISO Certification
- Relevant authorizations for the manufacture and wholesale distribution of radiopharmaceuticals

In collaboration with our partner company, Radiopharmacy Laboratory Ltd., we are also engaged in developing therapeutic radiopharmaceuticals. We welcome requests and suggestions for new research and development projects in nuclear medicine. Our capabilities in sterile injectables include formulation, process development, and manufacturing of sterile injectable drug products, suitable from small clinical trials to global commercial supply. We offer speed, flexibility, experience, and a broad set of capabilities to support your program.
At MEDI-RADIOPHARMA Ltd., we are dedicated to improving the lives of those we serve, including our employees, partners, patients, and the local communities in which we operate.

Our headquarters and manufacturing facilities are located in the metropolitan area of Budapest, conveniently near Budapest International Airport and the Hungarian highway system.

„At Medi-Radiopharma, our mission is to enhance healthcare and improve patient outcomes through our diverse portfolio of high-quality products.

Every day, I am inspired and proud of our ambitious and passionate team, as well as my father, whose foundational work has enabled us to become a key global player in our field."

WE ARE PROUD MEMBERS OF

NUCLEAR MEDICINE EUROPE
the industry association

EANM
EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE

29
YEARS OF EXCELLENCE

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Medi-MAA
kit for radiopharmaceutical preparation

Active substance	Each vial contains 2.5 mg macroaggregated human albumin (macrosalb).
Particle size	The macroaggregates number per vial is within the range of 3 - 8 ×10^6. In the labelled product the particle size distribution is as follows: More than 90 % of the particles are between 10 and 100 micrometres.
Indications	Pulmonary perfusion scintigraphy
Excipients	Human serum albumin Stannous chloride dihydrate Sodium chloride
Labelling activity	40-150 MBq (planar pulmonary perfusion) max. 200 MBq (SPECT pulmonary perfusion scintigraphy) For specific details please read the details of the SmPC.
Maximum labelling capacity	**6,85 GBq (185 mCi)**
Labelling volume	3-10 ml/vial
Storage	Store the kit in a refrigerator (2°C - 8°C)
Shelf life	**18 months**
Shelf life after radiolabeling	9,5 hrs, Store below 25°C
Registration numbers	Hungary: OGYI-T-24216/01 Austria: 441692 Belgium: BE661065 Bulgaria: 61944 Czech Republic: 88/556/20-C Denmark: 65593 Finland: 38749 France: 34009 550 938 3 1 Germany: early 2025. Italy: AIC n. 050543026 Luxemburg: 0942397 Malta: MA1241/00201 Norway: 21-13835 Poland: 28147 Spain: 89285 Sweden: 61617 The Netherlands RVG 127866
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Nano-Scan (99mTc-HSA nanosized colloid)
Tc-MR-7

Active substance	Human Serum Albumin nano sized colloid 500 micrograms
Particle size	At least 95 % of human albumin colloidal particles have a diameter ≤ 80 nm.

Indications	**Intravenous administration:**
	• Bone marrow scanning (The product is not suitable to study the haematopoietic activity of the bone marrow)
	• Inflammation scanning in areas other than the abdomen
	Subcutaneous administration:
	• Conventional lymphoscintigraphy to demonstrate integrity of the lymphatic system and differentiation of venous from lymphatic obstruction
	• Sentinel node detection in:
	  • Melanoma malignum
	  • Breast cancer

Excipients	• Stannous(II) chloride dihydrate • Glucose monohydrate • Sodium phosphate monobasic &Sodium phosphate dibasic
Dose for adults	**Intravenous application:** • Bone marrow scanning: 185-500 MBq (5.0-13.5 mCi) • Inflammation scanning: 370-500 MBq (10.0-13.5 mCi) **Subcutaneous administration:** • Lymphoscintigraphy: 18.5-110 MBq (0.5-3.0 mCi) **Sentinel node detection:** • Malignant melanoma: 40-100 MBq (1.08–2.7 mCi) • Breast cancer: 100-200 MBq (2.7-5.4 mCi)
Labelling activity	185 MBq - 5.5 GBq (5.0 mCi - 148.65 mCi)
Labelling volume	1-5 ml
Storage of cold kit	18 months from date of manufacturing, Do not store above 25°C
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Austria: 4-00046 Belgium: BE471911 Denmark: DK R 02248 Germany: 81340.00.00 Italy: 414/2012 Poland: 22470 Romania: 9353/2016/01-04 Spain: 76905 The Netherlands: RVG 112760 United Kingdom: PL 40129/0002
Marketing Authorization Holder	**Radiopharmacy Laboratory Ltd.** 2040 Budaörs, Gyár u. 2., Hungary

(for detailed actual information please read the current approved SmPC)

Senti-Scint (99mTc-HSA colloid)
Tc-MR-4

Active substance	Human Serum Albumin nano sized colloid (strength 1.0 mg)
Particle size	100-600 nm
Indications	Compound is suitable for • sentinel node lymphoscintigraphy in • breast cancer and • melanoma malignum
Excipients	• Stannous(II) chloride dihydrate • Glucose • Sodium phosphate monobasic & Sodium phosphate dibasic
Dose for adults	The recommended activity 60-100 MBq (1.6-2.7 mCi). 3-5 subcutaneous injections around the lesion. 20-20 MBq in volumes of 0.2-0.5 ml (0.54-0.54 mCi).
Labelling activity	maximum 5.5 GBq (148.65 mCi)
Labelling volume	1-5 ml
Storage of cold kit	18 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	maximum 6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8665/01 Belarus: 9915/12/17 Croatia: UP/I-530-09/11-01/19 Czech Republic: 88/100/01-C Slovak Republic: 88/0045/04-S Türkiye: 136/12
Marketing Authorization Holder	**Medi-Radiopharma Co., Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Nano-Albumon (^{99m}Tc-HSA nanosized colloid)

Tc-MR-3

Active substance	Human Serum Albumin nano sized colloid 1.0 mg
Particle size	More than 80% of the particles have a size maximum 100 nm
Indications	The labelled Nano-Albumon is suitable for • conventional lymphoscintigraphy • bone marrow scanning
Excipients	• Stannous(II) chloride dihydrate • Glucose • Sodium phosphate monobasic & Sodium phosphate dibasic
Dose for adults	Please check the SmPC for specific details
Labelling activity	maximum 2.2 GBq (59.46 mCi)
Labelling volume	1-3 ml
Storage of cold kit	18 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8664/01 Colombia: INVIMA 2018M-0018034 Czech Republic: 88/174/91-C
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Medi-MIBI 500 micrograms (^{99m}Tc-MIBI)

Tc-MR-1

Active substance	Sestamibi [tetrakis (1 isocyanide-2-methoxy-2-methylpropyl-) copper(I)] tetrafluoroborate 0.5 mg
Indications	The ^{99m}Tc labelled compound can be used for • Myocardial perfusion scintigraphy for the detection and localisation of coronary artery disease (angina pectoris and myocardial infarction) • Assessment of global ventricular function. First-pass technique for determination of ejection fraction and/or ECG-triggered, gated SPECT for evaluation of left ventricular ejection fraction, volumes and regional wall motion. • Scintimammography for the detection of suspected breast cancer when mammography is equivocal, inadequate or indeterminate. • Localisation of hyperfunctioning parathyroid tissue in patients with recurrent or persistent disease in both primary and secondary hyperparathyroidism, and in patients with primary hyperparathyroidism scheduled to undergo initial surgery of the parathyroid glands.
Excipients	• Stannous(II) chloride dihydrate • Sodium chloride • Tetrasodium pyrophosphate decahydrate • L-cysteine hydrochloride monohydrate • Glycine
Dose for adults	**Diagnosis of reduced coronary perfusion and myocardial infarction:** 400 – 900 MBq (10.8-24.3 mCi) **Diagnosis of ischaemic heart disease:** • Two-day protocol: 600–900 MBq/study (16.2-24.3 mCi) • One-day protocol: 400–500 MBq (10.8-13.5 mCi) **Assessment of global ventricular function:** 600-800 MBq injected as a bolus (16.2-21.6 mCi) **Scintimammography:** 700 - 1000 MBq injected as a bolus (18.9-27.0 mCi) **Localisation of hyperfunctioning parathyroid tissue:** 200 - 700 MBq injected as a bolus (5.4-18.9 mCi)
Labelling activity	**Up to 15 GBq (405.41 mCi)**
Labelling volume	1-5 ml
Storage of cold kit	30 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8762/01 Austria: 4-00035 Belgium: BE66332 Croatia: HR-H-769142649 Czechia: 88/884/92-C Denmark: DK. R. 02236 Germany: 90375.00.00 Greece: 71269 Italy: AIC n. 040312; AIC n. 040312011 6 vials/kit Luxembourg: 2025010008 Peru: RE-00097 Spain: 70755, National Code: 662762-4 6 vials/kit Taiwan: R00098 The Netherlands: RVG 131842 Türkiye: 135/54
Marketing Authorization Holder	**Radiopharmacy Laboratory Ltd.** 2040 Budaörs, Gyár u. 2., Hungary

(for detailed actual information please read the current approved SmPC)

Medi-Exametazime (^{99m}Tc-HM-PAO)
Tc-MR-14

Active substance
Exametazime 0.5 mg

Indications

Neurology:

- Evaluation of patients with cerebrovascular disease (specifically acute stroke, chronic ischemia, and transient ischemic attack)
- Presurgical lateralization and localization of epileptogenic foci.
- Evaluation of patients with suspected dementia (specifically Alzheimer's disease and frontotemporal dementia)
- Evaluation of patients with migraine
- Adjuvant technique in the diagnosis of brain death

Infectious or inflammatory diseases

- Localisation of abnormal foci guiding the aetiologic diagnosis in case of fever of unknown origin
- Diagnosis of infection in case of suspected osteomyelitis (with or without implants) and suspected hip or knee prosthesis infection.
- Detection of the extension of inflammation in case of inflammatory bowel disease.

Excipients
Stannous(II) chloride dihydrate
Tetrasodium pyrophosphate decahydrate

Dose for adults
Brain perfusion SPECT: 350-500 MBq (5.4-9.5 mCi)
Labelled leucocyte scintigraphy: 200 MBq (5.4 mCi)

Labelling activity
0.37-2.2 GBq (10-59.46 mCi)

Labelling volume
5 ml

Storage of cold kit
12 months from date of manufacturing,
Store at 2-8°C

Storage of labelled compound
1 hr,
Do not store above 25°C
Protect from light

Package size
6 vials

Registration numbers

Austria: Z.Nr.: 4-00051
Belgium: BE591537
Denmark: DK R 49482
Germany: 86253.00.0
Italy: AIC 042496
Luxembourg: 2021090180
The Netherlands: RVG 127837
Norway: 20-13828
Peru: RD8249
Portugal: 5628219
Slovenia: H/22/02922/001-004
Spain: 697827-6
Sweden: 61604
The Czech Republic: 88/539/20-C
United Kingdom: PL 40129/0001

Marketing Authorization Holder
Radiopharmacy Laboratory Ltd.
2040 Budaörs, Gyár u. 2., Hungary

(for detailed actual information please read the current approved SmPC)

Brain-Spect (^{99m}Tc-HM-PAO)
Tc-MR-5

Active substance
Exametazime 0.3 mg

Indications
Diagnostic study of

- Regional cerebral blood flow (stroke, carotid artery occlusion, transient ischaemic attack, migraine, tumours of the brain, dementia differential diagnosis,
- BRAIN-SPECT kit can be applied for detection, localisation of cortical areas with decreased perfusion, and to estimate the extent of the damage.
- Detection of affected cortical areas over 1-2 cm is feasible by planar gamma camera, the smaller areas can be detected by SPECT.

Excipients
Stannous(II) chloride dihydrate
Tetrasodium pyrophosphate decahydrate

Dose for adults
370-740 MBq (i.v. injection) (10-20 mCi)

Labelling activity
370-2200 MBq (10-59.5 mCi)

Labelling volume
5 ml

Storage of cold kit
12 months from date of manufacturing,
Store in a refrigerator (2-8°C)
Protect from light

Storage of labelled compound
1 hr,
Do not store above 25°C
Protect from light

Package size
6 vials

Registration numbers
Hungary: OGYI-T-8733/01
Belarus: 9904/12/17
Colombia: INVIMA 2015M-0015824
Czech Republic: 88/418/92-C
Türkiye: 135/53

Marketing Authorization Holder
Medi-Radiopharma Ltd.
2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Stabilised Brain-Spect
(Technetium [^{99m}Tc] exametazim HMPAO)
Tc-MR-15

Active substance	Exametazime 0.5 mg
Indications	**Brain scintigraphy:** • Regional cerebral blood flow scintigraphy (Stroke, reduced cerebral blood flow, ischemic attack, epilepsy, migraine, trauma, tumours of the brain, differential diagnosis of dementia). • The stabilised Brain-Spect 0.5 mg kit is able to recognise, localize the altered cerebral cortical tissue perfusion and to estimate the size of the damaged area.
Excipients	**Lyophilizate:** Stannous(II) chloride dihydrate Sodium-pyrophosphate-decahydrate **Cobalt(II)-chloride solution:** Cobalt(II)-chloride-hexahydrate Water for injection
Dose for adults	350-500 MBq intravenously (9.5-13.5 mCi)
Labelling activity	0.37-2.2 GBq (10-59.5 mCi)
Labelling volume	5 ml
Storage of cold kit	12 months from date of manufacturing, Store in refrigerator (2°C – 8°C)
Storage of labelled compound	Stabilised labelled product 6 hrs, Do not store above 25°C
Package size	6 injection vial containing powder and 6 injection vial containing solution in a carton box
Registration numbers	Hungary: OGYI-T-8733/02
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

Renoscint MAG3 1 mg (Technetium (^{99m}Tc) betiatide)
Tc-MR-16

Active substance	Betiatide To be used with sodium pertechnetate for the preparation of the diagnostic agent: Technetium (^{99m}Tc) tiatide.
Indications	After reconstitution and labelling with sodium pertechnetate solution, the diagnostic agent technetium (^{99m}Tc) tiatide may be used intravenously for the evaluation of nephrological and urological disorders in particular for the study of morphology, perfusion, and function of the kidney and characterisation of urinary outflow.
Excipients	Disodium tartrate dihydrate Stannous (II) chloride dihydrate Hydrochloric acid for pH adjustment
Dose for adults	37-185 MBq (1-5 mCi), depending on the pathology to be studied and the method to be used. Studies of renal blood flow or transport through the ureters generally require a larger dose than studies of intra-renal transport, whereas renography requires smaller activities than sequential scintigraphy.
Labelling activity	maximum 2960 MBq (80 mCi)
Labelling volume	10 ml
Storage of cold kit	18 months from date of manufacturing, Store in a refrigerator (2°C – 8°C)
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	1 pack contains 6 vials Sample package: 2 vials
Registration numbers	Hungary: OGYI-T-23275/01 (1x) OGYI-T-23275/02 (6x) Austria: 438272 Czech Republic: 88/832/16-C Denmark: DK R 58417 Germany: 98671.00.00 Italy: AIC 045669013 Poland: 24615 Spain: 82909 Switzerland Zul.-Nr.: 68106 United Kingdom: PL 27151/0001
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Mercapton (^{99m}Tc-DMSA)
Tc-MR-13

Active substance	Meso-2-3-dimercapto succinic acid
Indications	The Tc-99m labelled compound can be used for static (planar or tomographic) renal imaging: • Kidney scintigraphy, static imaging of kidney location • Determination of functional kidney weight • Determine the relative function (%) of the right and left kidneys
Excipients	Stannous(II) chloride dihydrate Sodium acetate trihydrate Ascorbic acid
Dose for adults	Recommended dose ranges for i.v. administration for adults: 50-140 MBq (1.35-3.78 mCi)
Labelling activity	Up to 3.7 GBq (100 mCi)
Labelling volume	2-5 ml
Storage of cold kit	12 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-9940/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Renon (^{99m}Tc-DTPA)
Tc-MR-11

Active substance	Acidum diaethylentriamino-pentaaceticum (DTPA) 10.0 mg
Indications	The ^{99m}Tc labelled compound can be used for: • After labeling with sterile ^{99m}Tc-pertechnetate solution, it is indicated for: • determination of glomerular filtration (GFR) • visualization of the kidney by sequential scintigraphy • renal perfusion studies • urinary tract studies • renal artery stenosis • estimation of transplanted kidney function • Vesico-urethral reflux • visualization of brain lesions (tumor, bleeding) • inhalation pulmonary scintigraphy (using a suitable nebulizer)
Excipients	Stannous(II) chloride dihydrate Sodium acetate trihydrate Ascorbic acid
Dose for adults	Glomerular filtration: 111-185 MBq (3-5 mCi) Renal perfusion: 370-740 MBq (10-20 mCi) Visualization of brain lesions: 370-740 MBq (10-20 mCi)
Labelling activity	Up to 8 GBq (216.2 mCi)
Labelling volume	1-5 ml
Storage of cold kit	24 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8816/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Makro-Albumon (^{99m}Tc-MAA)
Tc-MR-2

Active substance	Human Serum Albumin Macroaggregate 2.0 mg
Particle size	90% are between 10 and 100 µm (2-4x10^6 particles/vial)

Indications	The labelled MAA is suitable for
	• Pulmonary perfusion scintigraphy
	  • Pulmonary embolism and myocardial infarct
	  • Chronic circulatory failure
	  • Local respiratory distress
	  • Emphysema
	  • Tumour
	  • Inflammation
	• Visualisation of venous circulation
	  • Perfusion arterial scintigraphy of abdominal and retroperitoneal organs
	  • Detection of deep vein thrombosis in the lower extremities and pelvis
	  • Occlusion of the vena cava inferior

Excipients	Stannous(II) chloride dihydrate Glucose Ascorbic acid Sodium chloride
Dose for adults	Lung scintigraphy: 37-185 MBq (1-5 mCi)
Labelling activity	Up to 3.7 GBq (100 mCi)
Labelling volume	2-8 ml
Storage of cold kit	18 months from date of manufacturing, Store in a refrigerator (2°C -8°C) Protect from light
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8663-01 Belarus: 10085/13/18 Croatia: UP/I-530-09/11-01/20 Czech Republic: 88/177/91-C Russia: ЛС-002157 Türkiye: 136/11
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Skeleton (^{99m}Tc-MDP)
Tc-MR-10

Active substance	Methylene diphosphonic acid (MDP) 5.0 mg
Indications	• primary bone tumours imaging • bone metastases of other tumours (e.g. prostate, breast, lung cancer) • osteomyelitis • metabolic bone disease • Paget's disease • fractures • avascular necrosis • loosened/inflamed arthricular prosthesis • arthricular inflammations (rheumatoid arthritis)
Excipients	Stannous(II) chloride dihydrate Tetrasodium pyrophosphate decahydrate Ascorbic acid
Dose for adults	370-740 MBq (10-20 mCi)
Labelling activity	Up to 10 GBq (270.3 mCi)
Labelling volume	1-5 ml
Storage of cold kit	24 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	8 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8815/01 Taiwan: R00095
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

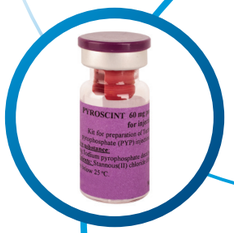
(for detailed actual information please read the current approved SmPC)

Bromo-Biliaron (^{99m}Tc-Br-IDA)
Tc-MR-12

Active substance	Mebrofenin [N-(3-bromo-2,4,6-trimethylphenylcarba-moil-methyl)-iminodiacetic acid] 5.00 mg
Indications	Hepatobiliary imaging • Hepatobiliary function studies • Evaluation of bile flow, and diagnosis of extrahepatic biliary obstruction, malfunctioning gall-bladder, gall-bladder inflammation, biliary duct artresia, biliary cysts or similar pathologic alterations of the biliary duct.
Excipients	Stannous(II) chloride dihydrate Sodium acetate trihydrate Ascorbic acid
Dose	Adult doses: 150-300 MBq (4.05-8.1 mCi) • Paediatric dose: to be adjusted to body weight. • 20 MBq is the minimal dose (also in babies) to obtain images of sufficient quality in kidney studies
Labelling activity	Up to 6.0 GBq (162.2 mCi)
Labelling volume	2-5 ml
Storage of cold kit	12 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-9941/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

Pyroscint (^{99m}Tc-PYP)
Tc-MR-9



Active substance	Sodium Pyrophosphate Decahydrate 60.0 mg
Indications	After radiolabelling with sodium (^{99m}Tc) pertechnetate solution, the solution obtained is indicated for • Bone scintigraphy • Cardiac scintigraphy, diagnosis of acute myocardial infarction After reconstitution with physiological sodium chloride solution in vivo or in vivo/in vitro red blood cell labelling for determination of blood volume and spleen scintigraphy.
Excipients	Stannous(II) chloride dihydrate Ascorbic acid
Dose for adults	Suggested dose ranges are different according to the type of investigation
Labelling activity	maximum 6.0 GBq (162.2 mCi)
Labelling volume	2-5 ml
Storage of cold kit	24 months from date of manufacturing, Do not store above 25°C Protect from light
Storage of labelled compound	6 hrs, Do not store above 25°C
Package size	6 vials
Registration numbers	Hungary: OGYI-T-8817/01
Marketing Authorization Holder	**Medi-Radiopharma Ltd.** 2030 Érd, Szamos u. 10-12., Hungary

(for detailed actual information please read the current approved SmPC)

MEDI-RADIOPHARMA

Your Global Nuclear Medicine Supplier

Delivering 30 years of trusted expertise in nuclear medicine

SERVICES

- **CDMO Services for Liquid and Lyophilized Products:** Scalable batch production from 1 to 300 litres
- **Comprehensive Tech Transfer & Validation:** Including microbiological, analytical, radioanalytical controls and stability testing
- **License for all isotopes** (including α-Emitters)
- **Animal testing, biodistribution studies and related imaging**
- **Analytical Method Development & Validation:** For both active drug substances and inactive/radioactive pharmaceutical products
- **Regulatory Services:** Complete support from eCTD preparation through regulatory approval
- **Drug Product Development:** QbD-driven formulation and process development for liquid and lyophilized injections, including validation and scale-up
- **API Synthesis:** Small molecule API synthesis under GMP compliance

MRP
MEDI-RADIOPHARMA
Your Global Nuclear Medicine Supplier

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