# 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 30 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.

WE ARE PROUD MEMBERS OF

NUCLEAR MEDICINE EUROPE
the industry association

EANM
EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE


„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.”

30 YEARS OF EXCELLENCE

# CONTENT



**Download our product catalogue here**

# **Medi-MAA** ($^{99m}$Tc-HSA macroaggregated human albumin)
## TC-MR-18

| | |
|---|---|
| **Active substance** | Each vial contains 2.5 mg macroaggregated human albumin (macrosalb). |
| **Particle size** | The number of macroaggregates per vial ranges between $3\times10^6$ and $8\times10^6$. In the labelled product, the particle size distribution is as follows: more than 90% of the particles are between 10 and 100 micrometres. |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for<br>• Pulmonary perfusion scintigraphy<br>• Radionuclide venography. |
| **Excipients** | Human serum albumin<br>Stannous chloride dihydrate (E512)<br>Sodium chloride |
| **Dose for adults** | Planar pulmonary perfusion scintigraphy: 40-150 MBq (1.08-4.05 mCi)<br>SPECT pulmonary perfusion scintigraphy: maximum 200 MBq (5.4 mCi) |
| **Labelling activity** | maximum 6.85 GBq (185 mCi) |
| **Labelling volume** | 3-10 ml/vial |
| **Storage conditions** | Store the kit in a refrigerator (2°C - 8°C). |
| **Shelf life** | 18 months |
| **Shelf-life and storage conditions after radiolabelling** | 9.5 hours<br>Store below 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary<br>Austria<br>Belgium<br>Bulgaria<br>Czech Republic<br>Denmark<br>Finland<br>France<br>Germany<br>Italy<br>Luxemburg<br>Malta<br>Norway<br>Poland<br>Spain<br>Sweden<br>The Netherlands |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

For the most recent detailed information, please visit our website and refer to the current approved Summary of Product Characteristics.

# **Nano-Scan** ($^{99m}$Tc-HSA nanosized colloid)
## Tc-MR-7


| | |
|---|---|
| **Active substance** | Each vial contains 500 micrograms nano-sized colloidal Human Serum Albumin |
| **Particle size** | At least 95% of human albumin colloidal particles have a diameter of ≤ 80 nm. |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for<br>**Intravenous administration:**<br>• Bone marrow scanning *(The product is not suitable to study the haematopoietic activity of the bone marrow.)*<br>• Inflammation scanning in areas other than the abdomen.<br>**Subcutaneous administration:**<br>• Lymphoscintigraphy to demonstrate integrity of the lymphatic system and differentiation of venous from lymphatic obstruction.<br>• Preoperative imaging and intraoperative detection of sentinel lymph nodes in melanoma, breast carcinoma, penile carcinoma, squamous cell carcinoma of the oral cavity and vulvar carcinoma. |
| **Excipients** | • Stannous(II) chloride dihydrate<br>• Glucose monohydrate<br>• Sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dihydrate |
| **Dose for adults** | **Intravenous administration:**<br>• Bone marrow scanning: 185-500 MBq (5.0-13.5 mCi)<br>• Inflammation scanning: 370-500 MBq (10.0-13.5 mCi)<br>**Subcutaneous administration:**<br>• Lymphoscintigraphy: 20-110 MBq (0.5-3.0 mCi)<br>• Sentinel node detection:<br>  • Melanoma: 10-120 MBq (0.27–3.24 mCi)<br>  • Breast carcinoma: 5-200 MBq (0.14-5.4 mCi)<br>  • Penile carcinoma: 40-130 MBq (1.08-3.5 mCi)<br>  • Squamous cell carcinoma of the oral cavity: 15-120 MBq (0.4-3.24 mCi)<br>  • Vulvar carcinoma: 60-120 MBq (1.62-3.24 mCi) |
| **Labelling activity** | 185 MBq - 5.5 GBq (5.0 mCi - 148.65 mCi) |
| **Labelling volume** | 1-5 ml |
| **Storage conditions** | Do not store above 25 °C.<br>Keep the vials in the outer carton in order to protect from light. |
| **Shelf life** | 18 months |
| **Shelf-life and storage conditions after radiolabelling** | 8 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Austria, Belgium, Denmark, Germany, Italy, Malta, Poland, Romania, Spain, The Netherlands, United Kingdom |
| **Marketing Authorization Holder** | **Radiopharmacy Laboratory Ltd.**<br>2040 Budaörs, Gyár u. 2., Hungary |

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# **Senti-Scint** ($^{99m}$Tc-HSA nanosized colloid)
## Tc-MR-4


| | |
|---|---|
| **Active substance** | Each vial contains 1 mg nano-sized colloidal Human Serum Albumin |
| **Particle size** | 100-600 nm |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for sentinel lymph node scintigraphy in patients with:<br>• breast cancer<br>• melanoma malignum. |
| **Excipients** | • Stannous(II) chloride dihydrate<br>• Sodium dihydrogen phosphate, disodium hydrogen phosphate<br>• Glucose |
| **Dose for adults** | The recommended activity 60-100 MBq (1.6-2.7 mCi). |
| **Labelling activity** | maximum 5.5 GBq (148.65 mCi) |
| **Labelling volume** | 1-5 ml |
| **Storage conditions** | Do not store above 25°C.<br>Protect from oxidizing agents and light. |
| **Shelf life** | 18 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary<br>Belarus<br>Croatia<br>Czech Republic<br>Slovak Republic<br>Turkey |
| **Marketing Authorization Holder*** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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

## Tc-MR-3


| | |
|---|---|
| **Active substance** | Each vial contains 1 mg nano-sized colloidal Human Serum Albumin |
| **Particle size** | More than 80% of the particles have a size maximum 100 nm |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for:<br>• lymphoscintigraphy<br>• bone marrow scanning. |
| **Excipients** | • Stannous(II) chloride dihydrate<br>• Glucose<br>• Sodium dihydrogen phosphate, disodium hydrogen phosphate |
| **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 conditions** | Do not store above 25°C.<br>Store in the original packaging in order to protect from light. |
| **Shelf life** | 18 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C, protected from light. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary<br>Colombia<br>Czech Republic |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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# Medi-MIBI ($^{99m}$Tc-MIBI)
## Tc-MR-1


**Active substance**

Each vial contains 0.5 mg Copper tetramibi tetrafluoroborate 500 micrograms

**Indications**

After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated 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**

Maximum 15 GBq (405.41 mCi)

**Labelling volume**

1-5 ml

**Storage conditions**

Do not store above 25°C.

**Shelf life**

30 months

**Shelf-life and storage conditions after radiolabelling**

8 hours
Do not store above 25°C.

**Pack size**

6 vials

**Authorized countries**

| | | |
|---|---|---|
| Austria | Germany | Peru |
| Belgium | Greece | Spain |
| Croatia | Hungary | Taiwan |
| Czechia | Italy | The Netherland |
| Denmark | Luxembourg | Turkey |

**Marketing Authorization Holder***

**Radiopharmacy Laboratory Ltd.**
2040 Budaörs, Gyár u. 2., Hungary

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# Medi-Exametazime ($^{99m}$Tc-HMPAO)
## Tc-MR-14


| | |
|---|---|
| **Active substance** | Each vial contains 0.5 mg exametazime |

**Indications**

**After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for**

**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)
- Adjuvant technique in the diagnosis of brain death.

**Infectious or inflammatory diseases**

- detection of sites of focal infection (e.g. abdominal abscess),
- investigation of pyrexia of unknown origin,
- evaluation of inflammatory conditions not associated with infection such as inflammatory bowel disease.

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| **Excipients** | Stannous(II) chloride dihydrate<br>Tetrasodium pyrophosphate decahydrate |
| **Dose for adults** | Brain perfusion SPECT: 555-1110 MBq (14.9-29.7 mCi)<br>For labelled leukocyte scintigraphy: 185-370 MBq (5.0-10.0 mCi) |
| **Labelling activity** | 0.37-2.2 GBq (10-60 mCi) |
| **Labelling volume** | 5 ml |
| **Storage conditions** | Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light. |
| **Shelf life** | 12 months |
| **Shelf-life and storage conditions after radiolabelling** | 60 minutes<br>Do not store above 25°C. Do not refrigerate or freeze after radiolabelling. |
| **Pack size** | 6 vials |
| **Authorized countries** | Austria, Belgium, Denmark, Germany, Italy, Luxembourg, The Netherlands, Norway, Peru, Portugal, Slovenia, Spain, Sweden, The Czech Republic, United Kingdom |
| **Marketing Authorization Holder** | **Radiopharmacy Laboratory Ltd.**<br>2040 Budaörs, Gyár u. 2., Hungary |

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# Brain-Spect ($^{99m}$Tc-HMPAO)
## Tc-MR-5


| | |
|---|---|
| **Active substance** | Each vial contains 0.3 mg exametazime |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for diagnostic study of<br>• Regional cerebral blood flow (vascular occlusion, reduced cerebral blood flow, ischemic attack, epilepsy, migraine, trauma, brain tumor, differential diagnosis of dementia)<br>• BRAIN-SPECT kit is suitable for detecting and localizing perfusion disorders in the cerebral cortex and estimating the size of the affected area<br>• Lesions larger than 1-2 cm can be detected with a planar gamma camera, while smaller or more subtle abnormalities can be examined with a SPECT device. |
| **Excipients** | Stannous(II) chloride dihydrate<br>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 conditions** | Store in a refrigerator (2-8°C). Store in the original packaging in order to protect from light. Keep away from oxidizing agents. |
| **Shelf life** | 12 months |
| **Shelf-life and storage conditions after radiolabelling** | 1 hour<br>Do not store above 25°C. Protect from light. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary<br>Belarus<br>Colombia<br>Czech Republic<br>Turkey |
| **Marketing Authorization Holder*** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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# Stabilised Brain-Spect ($^{99m}$Tc-HMPAO)
## Tc-MR-15


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|---|---|
| **Active substance** | Each vial contains 0.5 mg exametazime |
| **Indications** | **After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for brain scintigraphy:**<br>• Regional cerebral blood flow scintigraphy (vascular occlusion, reduced cerebral blood flow, ischemic attack, epilepsy, migraine, trauma, brain tumor, differential diagnosis of dementia).<br>• The stabilised Brain-Spect 0.5 mg kit is suitable for detecting and localizing perfusion disorders in the cerebral cortex and estimating the size of the affected area. |
| **Excipients** | **Lyophilizate:**<br>Stannous(II) chloride dihydrate<br>Sodium-pyrophosphate-decahydrate<br><br>**Cobalt(II)-chloride solution:**<br>Cobalt(II)-chloride-hexahydrate<br>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 conditions** | Store in refrigerator (2°C – 8°C). Store in the original packaging in order to protect from light. |
| **Shelf life** | 12 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C, protected from light. |
| **Pack size** | Pack of 6 vials with powder and 6 vials with solution for injection. |
| **Authorized countries** | Hungary |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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# **Renoscint MAG3** ($^{99m}$Tc-Betiatide)
## Tc-MR-16



| | |
|---|---|
| **Active substance** | Each vial contains 1 mg Betiatide |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated 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<br>Stannous (II) chloride dihydrate<br>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 conditions** | Store in refrigerator (2°C – 8°C).<br>Store in the original packaging in order to protect from light. |
| **Shelf life** | 18 months |
| **Shelf-life and storage conditions after radiolabelling** | 8 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary<br>Austria<br>Czech Republic<br>Denmark<br>Germany<br>Italy<br>Poland<br>Spain<br>Switzerland<br>United Kingdom |
| **Marketing Authorization Holder*** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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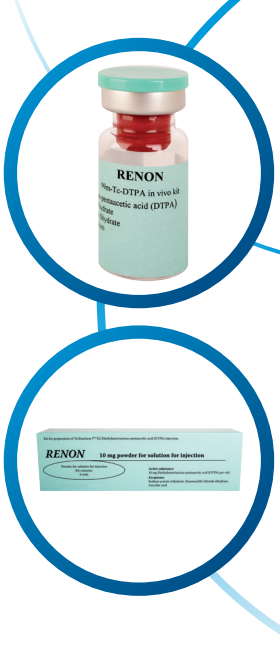
# Mercapton ($^{99m}$Tc-DMSA)
## Tc-MR-13


| | |
|---|---|
| **Active substance** | Each vial contains 3 mg meso-2,3-dimercapto succinic acid |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for static (planar or tomographic) renal imaging:<br>• Kidney scintigraphy, static imaging of kidney location<br>• Determination of functional kidney weight<br>• Determine the relative function (%) of the right and left kidneys. |
| **Excipients** | Stannous(II) chloride dihydrate<br>Sodium acetate trihydrate<br>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 conditions** | Do not store above 25°C. Store in the original packaging in order to protect from light. Keep away from oxidizing agents. |
| **Shelf life** | 12 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C, protected from light. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

For the most recent detailed information, please visit our website and refer to the current approved Summary of Product Characteristics.

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




| | |
|---|---|
| **Active substance** | Each vial contains 10 mg diethylenetriaminepentaacetic acid (DTPA). |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for<br>• determination of glomerular filtration (GFR)<br>• visualization of the kidney by sequential scintigraphy<br>• renal perfusion studies<br>• urinary tract studies<br>• renal artery stenosis<br>• estimation of transplanted kidney function<br>• Vesico-urethral reflux<br>• visualization of brain lesions (tumor, bleeding)<br>• inhalation pulmonary scintigraphy (using a suitable nebulizer). |
| **Excipients** | Stannous(II) chloride dihydrate<br>Sodium acetate trihydrate<br>Ascorbic acid |
| **Dose for adults** | Glomerular filtration: 111-185 MBq (3-5 mCi)<br>Renal perfusion: 370-740 MBq (10-20 mCi)<br>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 conditions** | Do not store above 25°C. Store in the original packaging. |
| **Shelf life** | 24 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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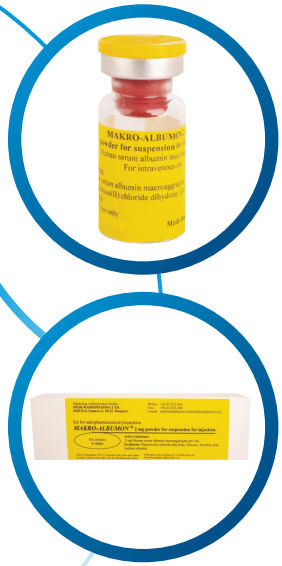
# Makro-Albumon ($^{99m}$Tc-MAA)
## Tc-MR-2



| | |
|---|---|
| **Active substance** | Each vial contains 2 mg macroaggregated Human Serum Albumin |
| **Particle size** | 90% are between 10 and 100 µm (2-4x$10^6$ particles/vial) |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for<br>• Pulmonary perfusion scintigraphy<br>  • Pulmonary embolism and myocardial infarct<br>  • Chronic circulatory failure<br>  • Local respiratory distress<br>  • Emphysema<br>  • Tumour<br>  • Inflammation.<br>• Visualisation of venous circulation<br>  • Perfusion arterial scintigraphy of abdominal and retroperitoneal organs<br>  • Detection of deep vein thrombosis in the lower extremities and pelvis<br>  • Occlusion of the vena cava inferior. |
| **Excipients** | Stannous(II) chloride dihydrate<br>Glucose<br>Ascorbic acid<br>Sodium chloride |
| **Dose for adults** | 37-185 MBq (1-5 mCi) |
| **Labelling activity** | Up to 3.7 GBq (100 mCi) |
| **Labelling volume** | 2-8 ml |
| **Storage conditions** | Store in a refrigerator (2°C -8°C).<br>Keep in the original packaging in order to protect from light. |
| **Shelf life** | 18 months |
| **Shelf-life and storage conditions after radiolabelling** | 8 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary, Czech Republic<br>Belarus, Russia<br>Croatia, Turkey |
| **Marketing Authorization Holder*** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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



| | |
|---|---|
| **Active substance** | Each vial contains 5 mg methylene diphosphonic acid (MDP) |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for<br>• primary bone tumours imaging<br>• bone metastases of other tumours (e.g. prostate, breast, lung cancer)<br>• osteomyelitis<br>• metabolic bone disease<br>• Paget's disease<br>• fractures<br>• avascular necrosis<br>• loosened/inflamed arthricular prosthesis<br>• arthricular inflammations (rheumatoid arthritis). |
| **Excipients** | Stannous(II) chloride dihydrate<br>Tetrasodium pyrophosphate decahydrate<br>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 conditions** | Do not store above 25°C. Keep away from oxidizing agents. |
| **Shelf life** | 24 months |
| **Shelf-life and storage conditions after radiolabelling** | 8 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary<br>Taiwan |
| **Marketing Authorization Holder*** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

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

| | |
|---|---|
| **Active substance** | Each vial contains 5 mg mebrofenin [N-(3-bromo-2,4,6 -trimethylphenylcarbamoil-methyl)-iminodiacetic acid] |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for hepatobiliary imaging.<br>• Hepatobiliary function studies<br>• 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<br>Sodium acetate trihydrate<br>Ascorbic acid |
| **Dose** | Adult doses: 150-300 MBq (4.05-8.1 mCi)<br>• Paediatric dose: to be adjusted to body weight.<br>• 20 MBq is the minimal dose (also in babies) to obtain images of sufficient quality in kidney studies. |
| **Labelling activity** | Up to 6 GBq (162.2 mCi) |
| **Labelling volume** | 2-5 ml |
| **Storage conditions** | Do not store above 25°C. Store in the original packaging in order to protect from light. Keep away from oxidizing agents. |
| **Shelf life** | 12 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C, protected from light. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

For the most recent detailed information, please visit our website and refer to the current approved Summary of Product Characteristics.

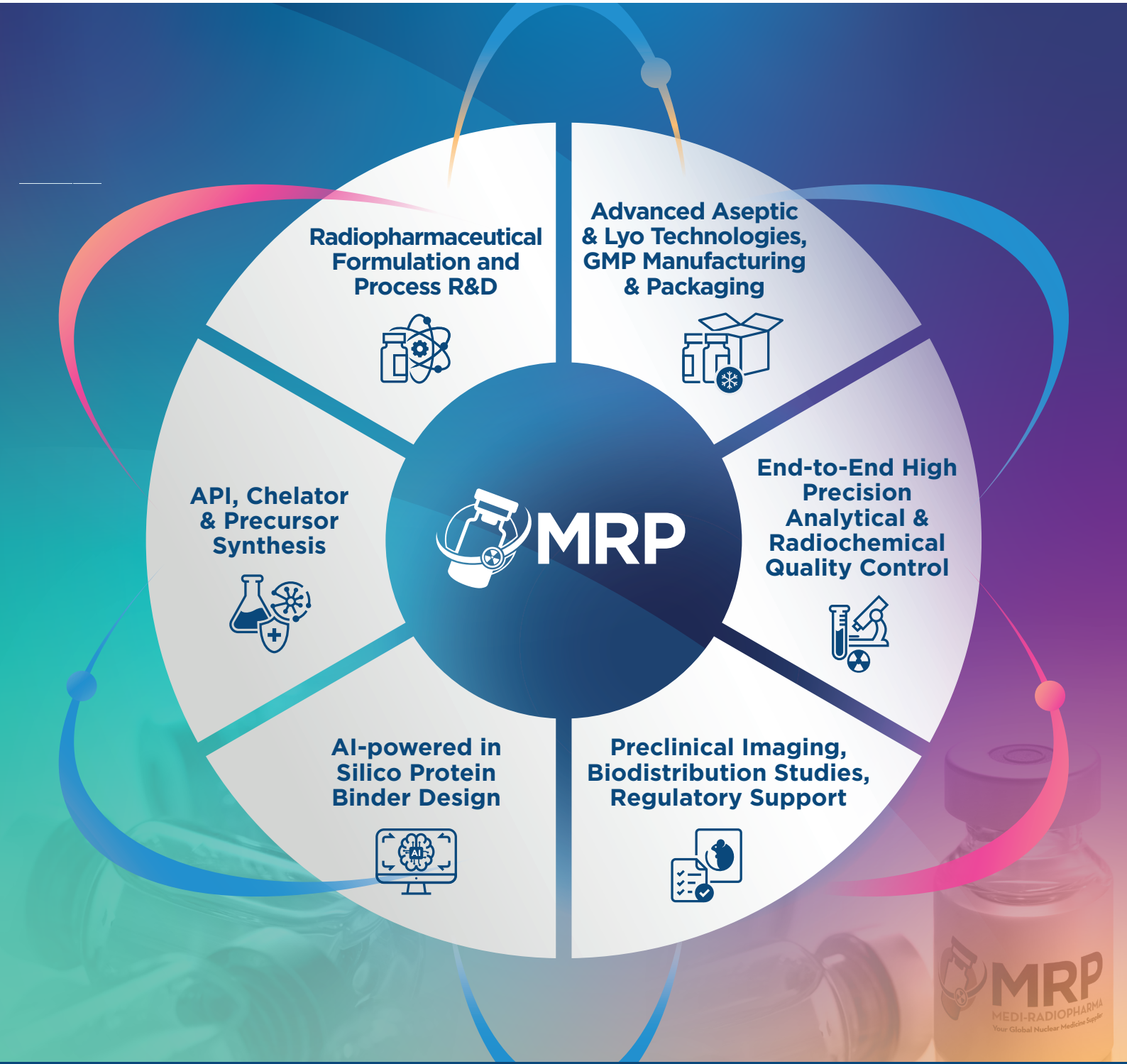
# Pyroscint ($^{99m}$Tc-PYP)
## Tc-MR-9


| | |
|---|---|
| **Active substance** | Each vial contains 60 mg Sodium Pyrophosphate Decahydrat |
| **Indications** | After radiolabelling with sodium pertechnetate ($^{99m}$Tc) solution, the solution obtained is indicated for<br>• Bone scintigraphy<br>• Cardiac scintigraphy, diagnosis of acute myocardial infarction.<br>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<br>Ascorbic acid |
| **Dose for adults** | Suggested dose ranges are different according to the type of investigation. |
| **Labelling activity** | maximum 6 GBq (162.2 mCi) |
| **Labelling volume** | 2-5 ml |
| **Storage conditions** | Do not store above 25°C. |
| **Shelf life** | 24 months |
| **Shelf-life and storage conditions after radiolabelling** | 6 hours<br>Do not store above 25°C. |
| **Pack size** | 6 vials |
| **Authorized countries** | Hungary |
| **Marketing Authorization Holder** | **Medi-Radiopharma Ltd.**<br>2030 Érd, Szamos u. 10-12., Hungary |

For the most recent detailed information, please visit our website and refer to the current approved Summary of Product Characteristics.

MRP

# YOUR ONE-STOP-SHOP CDMO FOR RADIOPHARMACEUTICALS AND STERILE DRUGS / REAGENTS

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