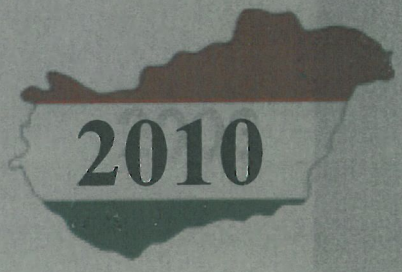
MEDI-RADIOPHARMA LTD

INTERNATIONAL CATALOGUE RADIOPHARMACEUTICALS

Tc-99m Labelled kits



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RENON

NAME OF THE MEDICINAL PRODUCT

RENON
Multidose kit
Kit for use in the preparation of Technetium-99m Diethylene triamine pentaacetate (DTPA) Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	
Diethylenetriamino pentaacetic acid (DTPA)	10.0 mg
Excipients:	
Sodium Acetate Trihydrate	40.0 mg
Stannous(II) Chloride Dihydrate	0.5 mg
Ascorbic Acid	0.1 mg

PHARMACEUTICAL FORM

The kit contains 6 vials of lyophilised, sterile, pyrogen free and inactive preparation sealed in nitrogen atmosphere, ready for one-step labelling with Sodium Pertechnetate [^{99m}Tc] Injection Ph.Eur. to yield a diagnostic radiopharmaceutical imaging agent. Labels for the reconstituted product and sanitising swabs (containing 70% isopropyl alcohol) are provided.

CLINICAL PARTICULARS

Diagnostic indications
After labelling with sodium pertechnetate (^{99m}Tc) solution the compound may be used for:

- Dynamic renal scintigraphy for perfusion, function and urinary tract studies.
- Measurement of glomerular filtration rate.
- Cerebral angiography and brain scanning. As an alternative method, when computed tomography and/or magnetic resonance imaging are not available.

After inhalation of the nebulized technetium(Tc-99m) labelled substance :

- Lung ventilation imaging.

After oral administration of the technetium(Tc-99m) labelled substance :

- Studies of gastro-oesophageal reflux and gastric emptying.

POSOLOGY AND METHOD OF ADMINISTRATION

In adults, the following administered doses are recommended (other doses may be justifiable).
For intravenous use :
Measurement of glomerular filtration rate from plasma: 1.8-3.7 MBq.
Measurement of glomerular filtration rate using gamma camera combined with sequential dynamic renal scanning: 37-370 MBq. Sequential scanning should begin immediately after injection. Optimal static imaging time is 1-hour post injection.
Brain scanning: 185-740 MBq.
For cerebral examinations, static images are obtained 1 hour and, if necessary, several hours after injection. Sequential dynamic scanning should begin immediately after injection.
For inhalation:
- Lung ventilation imaging:
  500-1000 MBq in nebuliser
  50-100 MBq in lung.

For oral use :
Study of gastro-oesophageal reflux and gastric emptying: 10-20 MBq.
Dynamic recording should be performed during the first minutes (up to 120 minutes for gastroduodenal transit).
Paediatric dose. The dose for children is adjusted according to body weight:

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq)} \times \text{child weight (kg)}}{70 \text{ kg}}$$

In some circumstances, dose adjustment according to surface area may be appropriate:

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq)} \times \text{child body surface } (m^2)}{1.73\ (m^2)}$$

In very young children (up to 1 year) a minimum dose of 20 MBq is necessary in order to obtain images of sufficient quality, when technetium(Tc-99m) pentetate (DTPA) is used for kidney studies.

PHARMACOLOGICAL PROPERTIES

Code No.:	MR-11
Hungarian Licence No.:	OGYI-T-8816/01
ATC code:	V09C A 01

INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Method of preparation

It is recommended that the contents of the vials should be reconstituted using sterile sodium pertechnetate(Tc-99m) free from any oxidising agent and to use as a diluter a 0.9% sterile solution of sodium chloride for additive-free injection. Preparation and use of the diagnostic agent should be carried out under aseptic conditions.

Determine the activity necessary according to the dose to be administered, the number of patients and the decay of the technetium-99m. The total activity per vial should not exceed 8.0 GBq. The final volume of the preparation should be between 1 and 5 ml. Place a vial of RENON in a lead container. Disinfect the vial septum using a bacteriostatic agent.

Inject aseptically into the vial the appropriate volume of sodium pertechnetate(Tc-99m) and the required quantity of diluter so as to be within the volume and activity limits of the preparation. Withdraw a volume of gas, equivalent to the volumes of the solutions, in order to balance the pressures.

Invert the vial several times in order to homogenise the preparation. Leave to react for a minimum of 15 minutes before use. Measure the activity using a correctly calibrated monitor. Complete the label using the marking parameters and label the vial and lead container. Ascending chromatography can check the labelling yield.

Keep the preparation under suitable shielding at room temperature and away from light.

SHELF LIFE

Shelf life of RENON in vivo kit (lyophilised non-radioactive components in glass ampoules closed with a rubber stopper and plastic-aluminium caps with turned up edge) is 24 months from the day of production. One paper box contains 6 ampoules. Radioactive labelling of the content of the individual ampoules can be done at different occasions within the expiry date shown on the label of the ampoule and the paper box. ^{99m}Tc-RENON injections must be used within 6 hours from labelling. The labelling procedure should be carried out in closed system.

SPECIAL PRECAUTION FOR STORAGE

RENON in vivo kit is to be stored at temperature below 25°C in its original packaging protected from light. ^{99m}Tc-DTPA injection is to be stored at temperature below 25°C in accordance with the national regulations on radioactive materials. This product is not to be administered directly to the patient. The contents of the vial are intended only for use in the preparation of radioactive ^{99m}Tc-technetium labelled injection, using the procedure described in user package insert. Radiopharmaceutical should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to licence the use of radionuclides.

MARKETING AUTHORISATION HOLDER

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MEDI-RADIOPHARMA LTD

MARKETING AUTHORISATION NUMBER(S)

Hungary: OGYI-T-8816/01 (For detailed information see product SmPC)

SKELETON

NAME OF THE MEDICINAL PRODUCT

SKELETON
Multidose kit
Kit for use in the preparation of Technetium-99m Methylene-diphosphonate (MDP) Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	
Methylene Diphosphonic Acid (MDP)	5.0 mg
Excipients:	
Stannous(II) Chloride Dihydrate	1.0 mg
Tetrasodium Pyrophosphate Decahydrate	20.0 mg
Ascorbic Acid	0.1 mg

PHARMACEUTICAL FORM

The kit containing 6 vials of lyophilised, sterile, pyrogen free and inactive preparation sealed in nitrogen atmosphere, ready for one-step labelling with Sodium Pertechnetate [99mTc] Injection Ph.Eur. to yield a diagnostic radiopharmaceutical imaging agent. Labels for the reconstituted product and sanitising swabs (containing 70% isopropyl alcohol) are provided.

CLINICAL PARTICULARS

Diagnostic indications
After reconstitution with sodium pertechnetate (Tc-99m) solution the agent may be used for bone scintigraphy, where it delineates areas of altered osteogenesis

POSOLOGY AND METHOD OF ADMINISTRATION

The average activity administered by a single intravenous injection is 500 MBq (300 - 700 MBq). Other activities may be justifiable.
Images obtained shortly after injection (e.g. in the so-called "3 phase bone scan" procedure) will only partly reflect metabolic bone activity. Late phase static scintigraphy should be performed not earlier than 2 hours after injection. The patient should void before scanning.
The dose to be administered to a child should be a fraction of the adult dose calculated from the body weight.
In very young children (up to 1 year) a minimum dose of 40 MBq is necessary in order to obtain images of sufficient quality.

PHARMACOLOGICAL PROPERTIES

Code No.:	MR-10
Hungarian Licence No.:	OGYI-T-8815/01
ATC code:	V09B A 02

INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Method of preparation
It is recommended that the contents of the bottles should be reconstituted using sterile sodium pertechnetate(Tc-99m) free from any oxidising agent and to use as a diluent a 0.9% sterile solution of sodium chloride for additive-free injection.
Preparation and use of the diagnostic agent should be carried out under aseptic conditions.

Determine the activity necessary according to the dose to be administered, the number of patents and the decay of the technetium-99m. The total activity per bottle should not exceed 10.0 GBq. The final volume of the preparation should be between 2 and 5 ml.
Place a bottle of SKELETON in a lead container.
Disinfect the bottle septum using a bacteriostatic agent.
Inject aseptically into the bottle the appropriate volume of sodium pertechnetate [^{99m}Tc] and the required quantity of diluent so as to be within the volume and activity limits of the preparation. Withdraw a volume of gas, equivalent to the volumes of the solutions, in order to balance the pressures.
Invert the bottle several times in order to homogenise the preparation.
Leave to react for a minimum of 15 minutes before use.
Measure the activity using a correctly calibrated monitor. Complete the label using the marking parameters and label the bottle and lead container.
The labelling yield can be checked by ascending chromatography.
Keep the preparation under suitable shielding at room temperature and away from light.

SHELF LIFE

Shelf life of SKELETON in vivo kit (lyophilised non-radioactive components in glass ampoules closed with a rubber stopper and plastic-aluminium caps with turned up edge) is 24 months from the day of production.
One paper box contains 6 ampoules. Radioactive labelling of the content of the individual ampoules can be done at different occasions within the expiry date shown on the label of the ampoule and the paper box.
^{99m}Tc-SKELETON (MDP labelled with radioactive Tc-99m radionuclide) injection must be used within 8 hours from labelling.
The labelling procedure should be carried out in closed system.

SPECIAL PRECAUTION FOR STORAGE

SKELETON in vivo kit is to be stored below 25°C in its original packaging.
^{99m}Tc-MDP injection is to be stored at temperature below 25°C in accordance with the national regulations on radioactive materials.
This product is not to be administered directly to the patient. The contents of the vial are intended only for use in the preparation of radioactive 99mTc-technetium labelled injection, using the procedure described in user package insert.
Radiopharmaceutical should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to licence the use of radionuclides.

MARKETING AUTHORISATION HOLDER

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MEDI-RADIOPHARMA LTD Rx

MARKETING AUTHORISATION NUMBER(S)

Hungary: OGYI-T-8815/01

(For detailed information see product SmPC)

MAKRO-ALBUMON

NAME OF THE MEDICINAL PRODUCT

MAKRO-ALBUMON, Kit for radiopharmaceutical preparation

QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of the active sustance:	
Human Serum Albumine Macroaggregate	2.0 mg
Excipient(s):	
Stannous(II) Chloride Dihydrate	0.2 mg
Ascorbic Acid	5.0 mg
Glucose	20.0 mg
Sodium Chloride	4.5 mg

PHARMACEUTICAL FORM

The kit is a lyophilised sterile and non-pyrogenic preparation sealed in nitrogen atmosphere, when labelled Technetium-99m-pertechnetate it is suitable for intravenous injection.

1 vial contains 2-4x10^6 particles, the size is mainly in range 10-90 µm. When a suspension of labelled particles is injected intravenously, the majority of particles are removed from the circulation on the first pass through pulmonary capillary bed, permitting pulmonary scintigraphy. The labelled material it is suitable for radionuclide venography of the lower leg or pelvis. The kit 6 vials, 6 self stick-on labels for the indication of the parameters of the labelled preparation and an instruction for use.

CLINICAL PARTICULARS

Therapeutic indications
After labelling with sterile ^{99m}Tc pertechnetate, the kit is suitable for investigations as follows:

- Perfusion lung 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

POSOLOGY AND METHOD OF ADMINISTRATION

- Adults, neonates, children and the elderly and mention of the posology for each age category
- Dosage (dose and interval) and duration
- Dosage adjustment in renal or liver insufficiency, dialysis
- Maximum tolerated daily dose and the maximum dose for an entire course of therapy
- Monitoring advice

^{99m}Tc-MAA can use only as intravenous bolus injection. One vial MAKRO-ALBUMON contains particles for 5-6 examinations. Therefore it is very important to pay attention that the whole content of one vial can give never for one patient and also can give never unlabelled aggregated human serum albumin. Before administration must draw there and back to vial the labelled MAKRO-ALBUMON to get homogenous solution. During this must avoid the form of foam.

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Technetium (99m-Tc) compounds
ATC code : V09DB01
Code: MR-2
Hungarian Licence No.: OGYI-T-8663

INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Place the vial containing the freeze-dried powder into a lead case with a wall 3 mm thick. Then, with a sterile needle aseptically inject 2-8 ml of ^{99m}Tc pertechnetate with the required activity (maximum 3.7 MBq) through the rubber cap into the vial. Before withdrawing the syringe from the vial, withdraw 2-8 cm^3 of gas from the space above the solution to normalise the pressure in the vial. Do not use a breather needle. Shake the vial until complete dissolution of the freeze-dried powder. Let it stand at 20-25 °C for 20 minutes, with periodic shaking in the meantime. Complete the label provided and attaches it to the vial.

SHELF LIFE

The expiry date for the kit is 18 months.
The labelled product should be used within 8 hours after reconstitution with sodium ^{99m}Tc-pertechnetate injection.
Sodium pertechnetate [^{99m}Tc] injection should comply with European Pharmacopoeia specification.

SPECIAL PRECAUTIONS FOR STORAGE

The kit should be stored below 25 °C-in the dark.
Do not store the labelled product above + 25 °C.
Storage should be in accordance with national regulations for radioactive materials.
The contents of the vial are intended only for use in the preparation of radioactive ^{99m}Tc-technetium labelled injection, using the procedure described in user package leaflet.

MARKETING AUTHORISATION HOLDER:

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MEDI-RADIOPHARMA LTD Rx

MARKETING AUTHORISATION NUMBER(S)

Hungary:	OGYI-T-8663
Czech Republic:	88/177/91-C
Slovak Republic	88/0120/02-S
Romania	3476/2003/01
Republic of Turkey	RF 04-0007

(For detailed information see product SmPC)

MERCAPTON

NAME OF THE MEDICINAL PRODUCT

MERCAPTON
Multidose kit
Kit for use in the preparation of Technetium-99m Dimercapto succinic acid (DMSA) Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	
Meso-2-3-dimercaptosuccinic Acid (DMSA)	3.00 mg
Excipients:	
Stannous(II) Chloride Dihydrate	0.33 mg
Sodium Acetate Trihydrate	32.80 mg
Ascorbic Acid	0.10 mg

PHARMACEUTICAL FORM

The kit contains a lyophilized, sterile, pyrogen free inactive powder for injection. Preparation sealed in nitrogen atmosphere, ready for one-step labelling with Technetium–99m for kidney scintigraphy. It comprises vials, self adhesive labels for stating the parameters of the labelled preparation, instruction for use and labels for the reconstituted product and sanitising swabs (containing 70% isopropyl alcohol) are provided.

CLINICAL PARTICULARS

Diagnostic indications
After reconstitution with sodium pertechnetate [99mTc] solution the agent may be used for:

- Static (planar or tomographic) renal imaging.
- morphological studies of renal cortex
- individual kidney function
- location of ectopic kidney

POSOLOGY AND METHOD OF ADMINISTRATION

In adults, the recommended activity is 30 to 120 MBq.
The image acquisitions may be performed as soon as 1 to 3 hours post-injection. Where there is renal impairment or obstruction, delayed views may be needed (6 to 24 hours respectively).
Paediatric dose: The dose for children is adjusted according to body weigh

$$\text{Paediatric dosage (MBq)} = \frac{\text{Adult dosage (MBq) x Child weight (Kg)}}{70}$$

In some circumstances, dose adjustment according to surface area may be appropriate:

$$\text{Paediatric dosage(MBq)} = \frac{\text{Adult dosage(MBq)x Child body surface (m2)}}{1.73}$$

PHARMACOLOGICAL PROPERTIES

Code No.:	MR-13
Hungarian Licence No.:	OGYI-T-9940/01
ATC code:	V09A A 02

INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Use aseptic technique throughout.

- Place one of the vials in a suitable shielding container and swab the rubber closure with the sanitising swab provided.
- Using a suitable syringe, inject a suitable quantity (see notes 1 and 2) of the eluate from a technetium-99m sterile generator into the shielded vial. Before removing the syringe from the vial, withdraw an equivalent volume of gas from the space above the solution to normalise the pressure in the vial.
- Invert the vial several times to ensure complete dissolution of the powder. Leave to react for a minimum of 15 minutes before use.
- Assay the total activity, complete the label provided and attach to the vial. The radiochemical purity can be determined as given below.

Notes:
1. Up to 3.7 GBq (100mCi) technetium-99m may be added to the vial.
2. Reconstitute with 2-5ml.
3. The use of a technetium-99m pertechnetate solution complying with the specification prescribed by the USP and BP/Ph. Eur. on Sodium Pertechnetate [99mTc] Injection will yield a preparation of an appropriate quality.

SHELF LIFE

Shelf life of MERCAPTON in vivo kit (lyophilised non-radioactive components in glass ampoules closed with a rubber stopper and plastic-aluminium caps with turned up edge) is 12 months from the day of production.
One paper box contains 6 ampoules. Radioactive labelling of the content of the individual ampoules can be done at different occasions within the expiry date shown on the label of the ampoule and the paper box. ^{99m}Tc-MERCAPTON (DMSA labelled with radioactive Tc-99m radionuclide) injection must be used within 6 hours from labelling. The labelling procedure should be carried out in closed system.

SPECIAL PRECAUTION FOR STORAGE

MERCAPTON in vivo kit is to be stored below 25°C in its original packaging.
^{99m}Tc-DMSA injection is to be stored at temperature below 25°C in accordance with the national regulations on radioactive materials. This product is not to be administered directly to the patient. The contents of the vial are intended only for use in the preparation of radioactive 99mTc-technetium labelled injection, using the procedure described in user package insert.
Radiopharmaceutical should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to licence the use of radionuclides.

MARKETING AUTHORISATION HOLDER

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MEDI-RADIOPHARMA LTD Rx

MARKETING AUTHORISATION NUMBER(S)

Hungary: OGYI-T-9940/01

(For detailed information see product SmPC)

PYROSCINT

NAME OF THE MEDICINAL PRODUCT

PYROSCINT, Multidose kit
Kit for use in the preparation of Technetium-99m tin pyrophosphate (PYP) Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	
Sodium Pyrophosphate Decahydrate	60.0 mg
Excipients:	
Stannous(II) Chloride Dihydrate	4,5 mg
Ascorbic Acid	0.1 mg

PHARMACEUTICAL FORM

The kit containing 6 vials of lyophilised, sterile, pyrogen free and inactive preparation sealed in nitrogen atmosphere, ready for one-step labelling with Sodium Pertechnetate [^{99m}Tc] Injection Ph.Eur. to yield a diagnostic radiopharmaceutical imaging agent. Labels for the reconstituted product and sanitising swabs (containing 70% isopropyl alcohol) are provided.

CLINICAL PARTICULARS

a) Bone scintigraphy, especially recommended in the following cases:
- Primer bone tumours
- Bone metastases of other tumours (e.g. prostate, breast, lung cancer)
- Osteomyelitis
- Metabolic bone disease
- Paget's disease

b) In vivo or in vivo/in vitro 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.
diagnosis and localisation of occult gastro-intestinal bleeding.
c) Determination of blood volume.
d) Spleen scintigraphy.

POSOLOGY AND METHOD OF ADMINISTRATION

Administration is by intravenous injection.
For bone scintigraphy studies and visualisation of acute myocardial infarctus
For bone scintigraphy studies and visualisation of acute myocardial infarctus Tc-99m-pyrophosphate is used directly. Recommended time of taking bone scintigraphy exposures 3-4 hors after administration.
Recommended time of imaging acute myocardial infarctus 60-90 minutes after administration.

Red blood cell (RBC) labelling methods
The stannous pyrophosphate lyophilisate (non radioactive substance) is first reconstituted with isotonic sodium chloride solution for injection.
In vivo method
Injection of reconstituted solution of the stannous pyrophosphate complex and consecutive injection of sodium pertechnetate(Tc-99m) 15 to 30 minutes later.
Modified in vivo method (in vivo/in vitro)
- Injection of the reconstituted solution of the stannous pyrophosphate complex for in-vivo "stannous loading" of RBC.
- In-vitro RBC labelling with sodium pertechnetate(Tc-99m) after withdrawal of a blood sample: 15 to 30 minutes after the first injection.
- Reinjection of the labelled Red Blood Cells

Denaturated Red Blood Cell Labelling
- In vitro Red Blood Cell labelling followed by denaturation of the erythrocytes e.g.; heating 49-50°C for 15 minutes.
- Reinjection of the labelled denaturated Red Blood Cells.

POSOLOGY

a) Bone scintigraphy studies and visualisation of acute myocardial infarctus
The quantity prepared at one labelling can be divided into3-6- individual doses. Labelling is to be carried out in the activity range of 3.0-6.0 GBq in the way that at the time of application each patient gets the required ^{99m}Tc-activity of 370-740 MBq.

b) Blood pool scintigraphy
The average activity administered by single injection after in vivo or in vitro labelling is 890 MBq (740-925 MBq).

c) Determination of blood volume
The average activity administered by single injection after in vitro labelling is 3 MBq (1-5 MBq).

d) Spleen scintigraphy
The average activity administered by single injection for in vitro labelling of denaturated erythrocytes is 50 MBq (20-70 MBq).
The optimal amount of non radioactive stannous tin for preparation of Red Blood Cells in vivo or in vitro is 0.05 µg to 1.25 µg per ml of the total blood volume of the patient (near 5,000 ml in a man of 70 kg weight). Scanning can be started immediately after injection of the tracer.

PHARMACOLOGICAL PROPERTIES

Code No.:	MR-9
Hungarian Licence No.:	OGYI-T-8817/01
ATC code:	V09B A 03

INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

Bone scintigraphy and myocardial infarct examination
Place the glass vial containing the feeze-dried material in a small lead pot of 3 mm wall thickness. In aseptic conditions the required activity of sterile Tc-99m-pertechnetate (3.0-6.0 GBq) is injected into the vial through the rubber cap with a sterile syringe. Mix up the vial thoroughly and let it stand for 15 minutes at room temperature (15-25 °C), while the labelling process takes place. Thereafter, the solution can be administered intravenously.

Imaging of the blood pool and measurement of the blood or globular volume
After reconstituting the PYROSCINT with 10 ml of 0.9% sterile sodium chloride for injection, inject intravenously the appropriate volume (table below) of stannous pyrophosphate corresponding to 10 µg of $SnCl_2.2H_2O$ per kilogram of body weight.
15 to 30 minutes later, administer 185 to 555 MBq (5 to 15 mCi) of sterile sodium pertechnetate(Tc-99m) to the patient in the case of imaging of the blood pool and 1.85 to 3.7 MBq (50 to 100 µCi) for measurement of the blood or globular volume.
Sequential imaging must be carried out immediately after injection of the solution of sterile sodium pertechnetate(Tc-99m). Static images can be taken 5 minutes to 3 - 4 hours after the injection.
Measurement of the blood or globular volume requires the collection of one or more samples of blood 20 to 60 minutes after injection of the sterile sodium pertechnetate(Tc-99m) solution.

Scintigraphy of the spleen
Take aseptically under heparin 3 to 5 ml of blood, 15 to 30 minutes after the injection of stannous pyrophosphate. Transfer the sample of blood to a 10 ml sterile vial containing a maximum volume of 0.5 ml of sterile sodium pertechnetate(Tc-99m) with an activity of between 18.5 and 55.5 MBq (0.5 to 1.5 mCi).
Slowly invert the flask several times to homogenise the preparation. Leave to react for 5 minutes before use.
Place the flask in a water bath at 50°C for 15 minutes. Invert the flask from time to time whilst keeping it in the water bath. Constantly check the temperature of the water bath.
Leave to cool for 2 minutes before use.
In adults, the activity of the erythrocytes preparation, labelled with technetium-99m, is 18.5 to 55.5 MBq (0.5 to 1.5 mCi).
In order to obtain optimum sensitivity, the imaging will be carried out 1 to 3 hours after injection.

SHELF LIFE

Shelf life of PYROSCINT **in vivo** kit is 24 months from the day of production.
^{99m}Tc-PYROSCINT injection must be used within 6 hours from labelling.

SPECIAL PRECAUTION FOR STORAGE

PYROSCINT in vivo kit is to be stored below 25°C in its original packaging.
^{99m}Tc-PYROSCINT injection is to be stored at temperature below 25°C in accordance with the national regulations on radioactive materials.

MARKETING AUTHORISATION HOLDER

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MEDI-RADIOPHARMA LTD Rx

MARKETING AUTHORISATION NUMBER(S)

Hungary: OGYI-T-8817/01

(For detailed information see product SmPC)

BROMO-BILIARON

NAME OF THE MEDICINAL PRODUCT

Multidose kit
Kit for use in the preparation of Technetium-99m Mebrofenin (BRIDA) Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	
N-(3-bromo-2,4,6-trimethylphenylcarbamoil-methyl)-iminodiacetic acid	5.00 mg
Excipients:	
Stannous(II) Chloride Dihydrate	0.50 mg
Sodium Acetate Trihydrate	60.00 mg
Ascorbic Acid	0.05 mg

PHARMACEUTICAL FORM

The kit containing 6 vials of lyophilised, sterile, pyrogen free and inactive preparation sealed in nitrogen atmosphere, ready for one-step labelling with Sodium Pertechnetate [^{99m}Tc] Injection Ph.Eur. to yield a diagnostic radiopharmaceutical imaging agent. Labels for the reconstituted product and sanitising swabs (containing 70% isopropyl alcohol) are provided.

CLINICAL PARTICULARS

After reconstitution with sodium pertechnetate (^{99m}Tc) solution for injection:

- Hepatobiliary imaging.
- Hepatobiliary function studies.

POSOLOGY AND METHOD OF ADMINISTRATION

The solution is administered intravenously to patients fasting for 6 hours prior to examination.
Adult doses
In adults, the dose is 150 to 300 MBq, other doses may be justifiable.
Pediatric doses
The dose to be administered in a child should be a fraction of the adult dose calculated from the body weight.
Paediatric Task Group, EANM)
In very young children (up to 1 year) a minimum dose of 20 MBq is necessary in order to obtain images of sufficient quality. Commencement of the examination as sequential or functional scintigraphy immediately after injection. Cholocystokinins or a fatty meal may be used to contract the gall bladder.

PHARMACOLOGICAL PROPERTIES

Code No.:	Tc- MR-12
Hungarian Licence No.:	OGYI-T-9941/01
ATC code:	V09D A 02

INSTRUCTION FOR PREPARATION OF RADIOPHARMACEUTICALS

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.

Suitable precautions should be taken concerning the activity eliminated by the patients in order to avoid any contamination. Waste must be disposed of according to national regulations.

Method of preparation

Place a vial containing the freeze-dried mixture in a convenient lead shield.

Aseptically introduce into the vial 2-5 ml ^{99m}Tc-sodium pertechnetate injection Ph. Eur. with a radioactivity maximum of 3.7 GBq.

- Do not use a breather needle.
- Relieve the excess of pressure in the vial by simply withdrawing an equal volume of gas in the syringe.
- Invert carefully a few times to dissolve the contents of the vial.
- Then allow to stand for about 5 min. at room temperature.
- Shake before withdrawing a dose.
- In no case should the preparation be left in contact with air.

SHELF LIFE

Shelf life of BROMO-BILIARON **in vivo** kit (lyophilised non-radioactive components in glass ampoules closed with a rubber stopper and plastic-aluminium caps with turned up edge) is 12 months from the day of production. One paper box contains 6 ampoules. Radioactive labelling of the content of the individual ampoules can be done at different occasions within the expiry date shown on the label of the ampoule and the paper box. ^{99m}Tc-BROMO-BILIARON injection must be used within 6 hours from labelling. The labelling procedure should be carried out in closed system.

SPECIAL PRECAUTION FOR STORAGE

BROMO-BILIARON in vivo kit is to be stored below 25°C in its original packaging. ^{99m}Tc-BRIDA injection is to be stored at temperature below 25°C in accordance with the national regulations on radioactive materials.

This product is not to be administered directly to the patient. The contents of the vial are intended only for use in the preparation of radioactive ^{99m}Tc-technetium labelled injection, using the procedure described in user package insert. Radiopharmaceutical should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to licence the use of radionuclides.

MARKETING AUTHORISATION HOLDER

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MEDI-RADIOPHARMA LTD

MARKETING AUTHORISATION NUMBER(S)

Hungary: OGYI-T-9941/01

(For detailed information see product SmPC)