**Indications:**
- brain scan for the investigation of the cerebral blood flow.
- Lung perfusion scintigraphy for diagnosis and exclusion of pulmonary embolism, follow-up after pulmonary embolism.
- Cardiac uptake scan for the study of function, morphology and perfusion of the kidneys and characterisation of urinary outflow.
- Detection of breast cancer when mammography is equivocal, inadequate or indeterminate, localisation of hyperfunctioning parathyroid tissue in patients with recurrent or persistent hyperparathyroidism, and in patients scheduled to undergo surgery of the parathyroid glands.
- Imaging kidneys and urinary tract.
- Scintimammography for the detection of breast cancer, also in case of previous mammography or mammography in equivocal, inadequate or indeterminate.
- Lymphatic scanning to demonstrate the integrity of the lymphatic system and differentiation of venous from lymphatic obstruction, Sentinel node detection in malignant melanoma and breast cancer.
- Imaging of the liver for detection of liver metastasis in patients with malignant neoplasms.
- Scintigraphy for diagnosis and exclusion of pulmonary embolism (pulmonary angiography).
- Imaging of the kidneys for diagnosis and exclusion of renal dysfunction.
- With cancer induction and a potential for development of hereditary defects.

**Undesirable effects:**
- Very rare: slight and temporary hypersensitivity reactions, flushing.
- Rare: fever, chills, sweating, very rarely (< 0.01 %) hypersensitivity reactions such as sensation of heat, dizziness, dyspnoea, pruritis, urticaria, rise or fall of blood pressure; low probability of cancer and hereditary defects.

**Contraindications:**
- Very rarely (< 0.01 %) hypersensitivity reactions such as flu-like symptoms, nausea and pruritus. Other hypersensitivity reactions have been described in predisposed patients. Not known to cause haptens or to lead to the formation of antigens.
- Undesirable effects: cancer, hereditary defects.

**Additional information:**
- Follow the general instructions for the use of Technetium (99mTc) Sestamibi obtained is indicated for myocardial perfusion scintigraphy for the detection and localisation of coronary artery disease and myocardial infarction, for the assessment of cardiac ventricular function ( gated SPECT for evaluation of left ventricular function, volumes and regional wall motion), SPECT angiography for the detection of breast cancer, also in case of previous mammography or mammography in equivocal, inadequate or indeterminate.
- Other disorders: Exposure to ionising radiation can lead to cancer or hereditary defects.

**Special precautions:**
- After reconstitution with Sodium pertechnetate (99mTc) solution for injection, the solution of Technetium (99mTc) Sestamibi obtained is indicated for myocardial perfusion scintigraphy for the detection and localisation of coronary artery disease and myocardial infarction, for the assessment of cardiac ventricular function (gated SPECT for evaluation of left ventricular function, volumes and regional wall motion), SPECT angiography for the detection of breast cancer, also in case of previous mammography or mammography in equivocal, inadequate or indeterminate.
- Other disorders: Exposure to ionising radiation can lead to cancer or hereditary defects.

**Package leaflet:**
- Available on medical prescription only.
<table>
<thead>
<tr>
<th>ROTOP-NanoHSA / NANOTOP</th>
<th>ROTOP-HSA Mikrosphären B20</th>
<th>CardioTOP / Cardiovist</th>
<th>ROTOP-MDP Neuroscan</th>
<th>MAG-3 Kit NephroMAG Mertascan</th>
<th>ROTOP-DTPA</th>
<th>ROTOP-DMSA</th>
<th>ROTOP-EHIDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>scintigraphic imaging and assessment of sentinel lymph nodes in tumor diseases</td>
<td>lung perfusion scintigraphy</td>
<td>myocardial perfusion scintigraphy, scintimammography, localisation of hyperfunctioning parathyroid tissue</td>
<td>bone scintigraphy</td>
<td>functional and static renal scintigraphy</td>
<td>quantitative determination of glomerular filtration rate</td>
<td>static renal scintigraphy</td>
</tr>
<tr>
<td>Active pharmaceutical ingredient</td>
<td>human albumin, denatured 0.5 mg more than 95 % smaller than 80 nm</td>
<td>human albumin, denatured 2.5 mg (300,000 - 500,000 microspheres, diameter 10 - 30 μm)</td>
<td>tetakis (2-methoxy-isobutylisonitrile)</td>
<td>copper(I)-tetrafluoroborate 1 mg</td>
<td>medronic acid (MDP) 5.0 mg</td>
<td>pentetic acid, sodium salt manufactured from pentetic acid: 5 mg sodium hydroxide: 1.32 mg</td>
<td>succimer (DMSA) 1.0 mg</td>
</tr>
<tr>
<td>Excipients</td>
<td>stannous chloride dihydrate 0.2 mg glucose 15 mg poloxamer 238 2 mg sodium phosphate 0.55 mg sodium phytate 0.25 mg</td>
<td>stannous chloride dihydrate 0.1 mg polyoxyl 80 0.648 mg rose bengal disodium 0.003 mg nitrogen (protective gas)</td>
<td>stannous chloride dihydrate 0.0076 mg</td>
<td>sodium chloride 0.46 mg</td>
<td>ascorbic acid 0.5 mg</td>
<td>hydrochloric acid 36%</td>
<td>stannous chloride dihydrate 0.25 mg</td>
</tr>
<tr>
<td>Adult dose</td>
<td>Subcutaneous administration: Lymphoscintigraphy: 18.5 - 110 MBq Scintigraphy of sentinel lymph nodes in tumors: 5 - 200 MBq</td>
<td>Diagnosis of reduced coronary perfusion and myocardial infarction: 400 - 900 MBq</td>
<td>500 MBq (Benign disease)</td>
<td>700 MBq (Malign disease)</td>
<td>400 - 500 MBq</td>
<td>10 - 200 MBq</td>
<td>1.8 - 3.7 MBq</td>
</tr>
<tr>
<td>Labelling activity up to</td>
<td>5.55 GBq</td>
<td>1.85 GBq</td>
<td>11 GBq</td>
<td>11.1 GBq</td>
<td>1 GBq</td>
<td>2.5 GBq</td>
<td>11.1 GBq</td>
</tr>
<tr>
<td>Incubation time</td>
<td>10 min</td>
<td>15 min boiling: 10 - 12 min thermal cycler: 12 min at 50 °C cooling cycle: 25 - 30 °C</td>
<td>10 min</td>
<td>15 min (no heating)</td>
<td>10 min</td>
<td>10 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Final dilution up to</td>
<td>up to 1:50 with saline solution (0.9%)</td>
<td>10 ml</td>
<td>10 ml</td>
<td>10 ml</td>
<td>8 ml</td>
<td>10 ml</td>
<td>10 ml</td>
</tr>
<tr>
<td>Shelf life after labelling</td>
<td>up to 15 yrs</td>
<td>6 hrs</td>
<td>6 hrs</td>
<td>6 hrs</td>
<td>6 hrs</td>
<td>4 hrs</td>
<td>3 hrs</td>
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<tr>
<td>Storage conditions</td>
<td>below 25 °C</td>
<td>2 - 8 °C</td>
<td>2 - 8 °C</td>
<td>2 - 8 °C</td>
<td>2 - 8 °C</td>
<td>2 - 8 °C</td>
<td>2 - 8 °C</td>
</tr>
<tr>
<td>Vials/ kit</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>
**ROTOP Pharmaka AG**

**Technetium-99m kits**

**ROTOP-NeuroPECT / Neurospect / Neuroscan**
- **Name of the medicinal product:** ROTOP-NeuroPECT
- **Composition:** 1 vial contains as active substance: 0.5 mg exametazime; excipients: stannous chloride dihydrate, ascorbic acid, sodium hydroxide, hydrochloric acid 36 %, nitrogen.
- **Indications:** brain scan for the investigation of the cerebral blood flow.
- **Contraindications:** Known: Side effects: very rarely (< 0.01 %) hypersensitivity reactions in form of urticaria or angioedema, anaphylactic reactions. Marketing Authorization Holder: ROTOP Pharmaka AG, Bautzner Landstraße 40, 01328 Dresden, Germany. Marketing Authorization Number (Germany): 305288.00.00. Available on medical prescription only.

**ROTOP-MAG-3 Kit / NephroMAG / Mertioscan**
- **Name of the medicinal product:** MAG-3 Kit / NephroMAG / Mertioscan
- **Composition:** The kit contains two different vials: (1) and (2). Vial (1) contains as active substance: 2.5 µg of human albumin, denatured (300,000 - 500,000 microspheres, Ø: 10 - 20.0 µm); stannous chloride dihydrate, sodium (R,R)-tartrate dihydrate, sodium hydroxide, hydrochloric acid 36 %, nitrogen as protective gas. Vial (2) contains 2.5 ml phosphate buffer solution.
- **Indications:** Use vial (1) for the preparation of radioactive mixture. Use vial (2) for dilution. 
  - for the evaluation of nephrological and urological disorders in particular confirmation of a missing kidney function on multicystic kidneys;
  - for the verification of renal function in conditions of reduced or increased renal perfusion;
  - for the evaluation of renal function in cases of suspected renal blood flow disorders or renal masses;
  - for the detection of residual renal function in patients scheduled to undergo surgery of the parathyroid glands.
- **Contraindications:** Know: Side effects: very rarely (< 0.01 %) hypersensitivity reactions such as urticaria, angioedema, anaphylactic reactions. Marketing Authorization Holder: ROTOP Pharmaka AG, Bautzner Landstraße 40, 01328 Dresden, Germany. Marketing Authorization Number (Germany): 305288.00.00. Available on medical prescription only.

**ROTOP-NanoHSA / NANOTOP**
- **Name of the medicinal product:** ROPHSA Microspheres 520
- **Composition:** 1 vial contains as active substance: 25 mg human albumin, denatured (100,000 - 200,000 microspheres, Ø: 20 - 30.0 µm); stannous chloride dihydrate, sodium (R,R)-tartrate dihydrate, sodium hydroxide, hydrochloric acid 36 %, nitrogen as protective gas.
- **Indications:** Lung perfusion scintigraphy for diagnosis and exclusion of pulmonary embolism, follow-up after pulmonary embolism. Marketing Authorization Holder: ROTOP Pharmaka AG, Bautzner Landstraße 40, 01328 Dresden, Germany. Marketing Authorization Number (Germany): 305288.00.00. Available on medical prescription only.

Please see the Package Leaflet and Summary of Product Characteristics included with your product for full details.