**PRODUCT OVERVIEW**

Please consider the complete information in the Package Leaflet and the Summary of Product Characteristics!

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<tbody>
<tr>
<td>Indication</td>
<td>Sodium Dureide in solution for injection of gadoteridol for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>Calcium Disodium Oxalate for injection, for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>Polymethylmethacrylate/Methylmethacrylate for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>HSA/Martiscint for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>Neur+Scint for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>MAG-3/X (NephroIMAG/Martiscint/EMLAG) for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>DTPA for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>DMSA for diagnostic imaging of the brain, spinal cord and other tissues</td>
<td>EDHDA for diagnostic imaging of the brain, spinal cord and other tissues</td>
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<td>Component</td>
<td>Sodium Dureide</td>
<td>Calcium Disodium Oxalate</td>
<td>Polymethylmethacrylate/Methylmethacrylate</td>
<td>HSA/Martiscint</td>
<td>Neur+Scint</td>
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<td>Shelf life after production</td>
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<td>15 months</td>
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**Adenosine**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Indication</th>
<th>Active pharmaceutical ingredient</th>
<th>Manufacturer site</th>
<th>Storage</th>
<th>Shelf life after production</th>
<th>Registered in</th>
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<td>Shelf life after production</td>
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<tr>
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<td>PL, UK, PL,</td>
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</tbody>
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**Active pharmaceutical ingredient**

- Sodium Dureide
- Calcium Disodium Oxalate
- Polymethylmethacrylate/Methylmethacrylate
- HSA/Martiscint
- Neur+Scint
- MAG-3/X (NephroIMAG/Martiscint/EMLAG)
- DTPA
- DMSA
- EDHDA

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**Excipients**

- Sodium Dureide
- Calcium Disodium Oxalate
- Polymethylmethacrylate/Methylmethacrylate
- HSA/Martiscint
- Neur+Scint
- MAG-3/X (NephroIMAG/Martiscint/EMLAG)
- DTPA
- DMSA
- EDHDA

---

**Indication**

- Sodium Dureide in solution for injection of gadoteridol for diagnostic imaging of the brain, spinal cord and other tissues
- Calcium Disodium Oxalate for injection, for diagnostic imaging of the brain, spinal cord and other tissues
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- DTPA for diagnostic imaging of the brain, spinal cord and other tissues
- DMSA for diagnostic imaging of the brain, spinal cord and other tissues
- EDHDA for diagnostic imaging of the brain, spinal cord and other tissues

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**Storage**

- 2°C to 8°C
- 2°C to 8°C
- 2°C to 8°C
- 2°C to 8°C
- 2°C to 8°C
- 2°C to 8°C
- 2°C to 8°C
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- 2°C to 8°C
Name of the medicinal product: Pertector 2.3 - 57.1 GBq radionuclide generator

Composition:
Pertector radionuclide generator contains as active substance:
sodium molybdate (99Mo) / sodium pertechnetate (99mTc)
excipients:
Sodium chloride, Water for injection, Benzododecinium bromide (bacteriostatic solution), Nitric acid (pH adjustment), Sodium hydroxide (pH adjustment)

Indications:
This medicinal product is for diagnostic use only. The eluate from the radionuclide generator (sodium pertechnetate (99mTc) injection) is indicated for:
- labelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution;
- Thyroid scintigraphy: direct imaging and measurement of thyroid uptake to give information on the size, position, nodularity and function of the gland in case of thyroid disease;
- Salivary gland scintigraphy: diagnosis of chronic sialadenitis (e.g. Sjögren’s Syndrom) as well as assessment of salivary gland function and duct patency in salivary glands disorders and monitoring of the response to therapeutic interventions (in particular radio iodine therapy);
- Location of ectopic gastric mucosa (Meckel’s diverticulum);
- Lacrimal duct scintigraphy: to assess functional disorders of lacrimation and monitoring of the response to therapeutic interventions;
- Shunt scintigraphy: after injection of the sterile sodium(99mTc)pertechnetate solution into a Rickham reservoir to test the patency of ventricular shunts in hydrocephalus.

Contraindications:
Hypersensitivity to the active substance or to any of the excipients. Information on the contraindications to the use of a kit for a radiopharmaceutical for radiolabelling can be found in the summary of product characteristics and the package leaflet for the kit.

Undesirable effects:
- Immune system disorders:
  Frequency unknown: Anaphylactoid reactions (e.g. dyspnoea, coma, urticaria, erythema, rash, pruritus, oedema at various location e.g. face oedema);
- Nervous system disorders:
  Frequency unknown: Vasovagal reactions (e.g. syncope, tachycardia, bradycardia, dizziness, headache, vision blurred, flushing);
- Gastrointestinal disorders:
  Frequency unknown: Vomiting, nausea, diarrhea;
- General disorders and administration site conditions:
  Frequency unknown: Injection site reactions due to extravasation (e.g. cellulitis, pain, erythema, swelling). Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 400 MBq is administered these adverse reactions are expected to occur with a low probability.

Marketing Authorisation Holder:
ROTOP Pharmaka GmbH, Bautzner Landstraße 400, 01328 Dresden, Germany

Marketing Authorisation Number:
80873.00.00 (Germany)

Available on medical prescription only.

To speak with a member of our Customer Services team please call +49 351 26 310 212.
Available on medical prescription only.

80873.00.00 (Germany)

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Contraindications:

This medicinal product is available on medical prescription only. 

Marketing Authorization Number:

Name of the medicinal product:

Pharmacy only medicine.

Marketing Authorization Number:

Contraindications:

very rarely (< 0.01 %) hypersensitivity reactions such as localized or generalized rash, itching, hypotension, headache, dizziness, nausea and vomiting; low proba-

nitrogen.

ROTOP-DMSA

Pharmacy only medicine.

Marketing Authorization Number:

Name of the medicinal product:

PL 34397/0001 (UK)

Prescription only medicine.

immunoglobulin G (IgG) fraction of horse serum (ISF) and sodium pertechnetate (99mTc) solution for injection.

Indications:

Quantitative determination of the glomerular filtration rate;

Indications:

Tektrotyd is supplied as kit consisting of two vials which cannot be used separately. Vial I contains

ROTOP Pharmaka GmbH, Bautzner Landstraße 400, 01328 Dresden, Germany

Marketing Authorization Holder:

ROTOP-Neurospect

3003667.00.00 (Germany)

undetermined:

Uncommon: Nausea; Rare: Abdominal pain.

Activities on the day of delivery:

ROTOP Pharmaka GmbH

Product overview

To speak with a member of our Customer Services team please call +49 351 26 310 212.

undetermined:

Mild and disappear rapidly (usually within 30 seconds).

Common side effects (>1/100, <1/10):

drugs, magnesium sulphate (E528), Potassium, Sodium chloride (E508), Stannous chloride dihydrate, sodium citrate dihydrate, D-mannitol (E421).

Name of the medicinal product:

Excipients:

Set of 400 MBq of 99mTc-EDDA

ROTOP-EHIDA

Eur.) and water for injection (Ph. Eur.)

Nitrogen (as protective gas).

Indications:

function (gated SPECT for evaluation of left ventricular ejection fraction, volumes and regional wall motion), Scintimammography for the detection of breast cancer, detection of breast cancer when mammography is

Undesirable effects:

Mild and disappear rapidly (usually within 30 seconds).

Common side effects (>1/100, <1/10):

as microspheres for use in liver imaging and embolisation.

An injection vial containing elution solution

/ preselection of elution volume

/ receiptable for eluate

/ 16 injection vials containing elution solution

(5 % NaCl solution, 10 ml)

/ 16 connection 5 ml kit as receptacles for eluates

/ lead shielding for one or two generators

/ 10 injection vial containing elution solution

(3 % NaCl solution, 10 ml)

/ 10 connection 5 ml kit as receptacles for eluates

Pertector

Mc-99/Tc-99m radionuclide generator

Our service contains

high reliability in supply

preselection of elution volume

easy handling.

registered in Germany, Switzerland and the UK.

To speak with a member of our Customer Services team please call +49 351 26 310 212.

Undesirable effects:

Marked hypotension and arrhythmias including ventricular fibrillation, ventricular

Riglycine (mertiatide). Vial (2) contains 2.5 ml phosphate buffer solution.

Composition:

active substance:

excipients:

Active substance:

active substance:

5 mg adenosine

ROTOP-MDP

Pharmacy only medicine.

Marketing Authorization Number:

ROTOP-DTPA

Available on medical prescription only.

Name of the medicinal product:

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