CONTENTS

Company profile .................................................................................................................. 4

Radionuclide generator
Poltechnet 8-175 GBq radionuclide generator $^{99}$Mo/$^{99m}$Tc ........................................ 5
Accessories for radionuclide generator ............................................................................... 8
Syringe shieldings ................................................................................................................. 9

Kits for labelling with $^{99m}$Tc
PoltechColloid, 0.17 mg .................................................................................................... 10
PoltechDMSA, 1 mg .......................................................................................................... 11
PoltechDTPA, 13.25 mg .................................................................................................. 12
PoltechMBrIDA, 20 mg .................................................................................................... 13
PoltechMDP, 5 mg ........................................................................................................... 14
PoltechMIBI, 1 mg ........................................................................................................... 15
PoltechRBC, 13.40 mg .................................................................................................... 16
Techimmuna, 2 mg ......................................................................................................... 17
$^{99m}$Tc-Tektrotyd 16 $\mu$g .................................................................................................. 18

Radiopharmaceuticals
Hippurate-$^{131}$I for injection .............................................................................................. 19
MIBG-$^{131}$I for diagnostic use, solution for injection ......................................................... 20
MIBG-$^{131}$I for therapeutic use, solution for injection ......................................................... 21
MIBG-$^{123}$I for diagnostic use, solution for injection ......................................................... 22
$\text{Na}_2\text{H}_{32}\text{PO}_4$ sodium orthophosphate, solution for injection .................................. 23
Sodium iodide Na$^{131}$I POLATOM, capsules for diagnostic use ....................................... 24
Sodium iodide Na$^{131}$I POLATOM, capsules for therapeutic use ..................................... 25
Sodium iodide Na$^{131}$I, solution for injection ................................................................. 26
Strontium chloride $^{89}$SrCl$_2$ POLATOM 37.5 MBq/ml solution for injection ................. 27

Radiopharmaceutical precursors
ItraPol($^{90}$Y), radiopharmaceutical precursor, solution .................................................... 28
LutaPol($^{177}$Lu), radiopharmaceutical precursor, solution ................................................... 29

Definitions, units, decay tables ......................................................................................... 30
Radioisotope Centre **POLATOM** is the research and development organization in the structure of the National Centre for Nuclear Research, state owned research institute, located in Otwock near Warsaw. Maria Research Reactor, the main irradiation facility in Poland, is in the close vicinity.

**POLATOM** carries out scientific research and development programs oriented at the application of radioisotopes in nuclear medicine, industry and science. Results of our research programs and innovation activities in the development of radiopharmaceuticals can be directly implemented in the GMP certified production and QC facilities. Sealed radiation sources, standard solutions and reference sources as well as related services are also offered.

Quality Assurance System established at the Radioisotope Centre **POLATOM** in the area of manufacturing, sales, dispatching and transport of radioactive materials is certified according to PN-EN ISO 9001:2009 and the criteria of Internal Control System.

In recent years **POLATOM** launched manufacture of several innovative products, among them \(^{99m}\text{Tc}\)-Tektrotyd radiopharmaceutical kit for diagnostic imaging of tumors expressing somatostatin receptors, useful in oncology, or ItraPol \(^{90}\text{Y}\) solution for radiolabeling) and LutaPol \(^{177}\text{Lu}\) solution for radiolabeling) as radiopharmaceutical precursors for radiolabeling of peptides and other biomolecules for therapy of cancer.

**POLATOM** is a world famous supplier of high quality radiopharmaceuticals and diagnostic kits for nuclear medicine and important manufacturer of radiochemical products for customers all over the world. Our products are exported to more than 70 countries.
Poltechnet 8-175 GBq
radionuclide generator $^{99}\text{Mo}/^{99m}\text{Tc}$
code: MTcG-4

- Qualitative and quantitative composition:
  Sodium pertechnetate ($^{99m}\text{Tc}$) injection is produced by means of a ($^{99}\text{Mo}/^{99m}\text{Tc}$) generator. Technetium ($^{99m}\text{Tc}$) decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6.01 hours to technetium-99 which, in view of its long half-life of $2.13 \times 10^{5}$ years, can be regarded as quasi stable.

The radionuclide generator containing the parent isotope $^{99}\text{Mo}$, adsorbed on a chromatographic column delivers sodium pertechnetate $^{99m}\text{Tc}$ injection in sterile solution.

The $^{99}\text{Mo}$ on the column is in equilibrium with the formed daughter isotope $^{99m}\text{Tc}$. The generators are supplied with the following $^{99}\text{Mo}$ activity amounts at activity reference time which deliver the following technetium-99m amounts, assuming a 100% theoretical yield and 24 hours time from previous elution and taking into account that branching ratio of $^{99}\text{Mo}$ is about 87%.

Examples of activities of radionuclide generators:

<table>
<thead>
<tr>
<th>$^{99m}\text{Tc}/^{99}\text{Mo}$ activity [GBq] at production date</th>
<th>8.0</th>
<th>14</th>
<th>21</th>
<th>28</th>
<th>35</th>
<th>42</th>
<th>48</th>
<th>53</th>
<th>60.6</th>
<th>64</th>
<th>69</th>
<th>78.9</th>
<th>88</th>
<th>100.6</th>
<th>125</th>
<th>142.9</th>
<th>141</th>
<th>161.1</th>
<th>175</th>
<th>200</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{99m}\text{Tc}$ activity (maximal theoretical eluable activity at calibration date, 5 days after production, at 12am CET) [GBq]</td>
<td>2.3</td>
<td>4.0</td>
<td>6.0</td>
<td>8.0</td>
<td>10</td>
<td>12</td>
<td>15</td>
<td>18</td>
<td>20</td>
<td>25</td>
<td>35</td>
<td>40</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$^{99}\text{Mo}$ activity (at calibration date, 5 days after production, at 12am CET) [GBq]</td>
<td>2.6</td>
<td>4.5</td>
<td>6.8</td>
<td>9.2</td>
<td>11</td>
<td>14</td>
<td>17</td>
<td>21</td>
<td>22</td>
<td>29</td>
<td>41</td>
<td>46</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The technetium ($^{99m}\text{Tc}$) amounts available by a single elution depend on the real elution yield of generator itself declared by manufacturer and approved by National Competent Authority (NCA).
### Expected radioactivity of eluted $^{99m}$Tc on each exploitation day from the generators within standard range of nominal activities:

<table>
<thead>
<tr>
<th>GBq</th>
<th>4.00</th>
<th>5.00</th>
<th>6.00</th>
<th>7.50</th>
<th>8.00</th>
<th>10.00</th>
<th>12.00</th>
<th>15.00</th>
<th>18.00</th>
<th>20.00</th>
<th>23.00</th>
<th>25.00</th>
<th>30.00</th>
<th>35.00</th>
<th>40.00</th>
<th>50.00</th>
<th>60.00</th>
<th>82.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>1.5</td>
<td>3.1</td>
<td>6.1</td>
<td>12.2</td>
<td>24.4</td>
<td>48.8</td>
<td>97.6</td>
<td>195.3</td>
<td>390.5</td>
<td>781.0</td>
<td>1562</td>
<td>3124</td>
<td>6248</td>
<td>12497</td>
<td>24994</td>
<td>49988</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3.1</td>
<td>6.1</td>
<td>12.2</td>
<td>24.4</td>
<td>48.8</td>
<td>97.6</td>
<td>195.3</td>
<td>390.5</td>
<td>781.0</td>
<td>1562</td>
<td>3124</td>
<td>6248</td>
<td>12497</td>
<td>24994</td>
<td>49988</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>4.6</td>
<td>9.2</td>
<td>18.4</td>
<td>36.8</td>
<td>73.6</td>
<td>147</td>
<td>294</td>
<td>588</td>
<td>1176</td>
<td>2352</td>
<td>4704</td>
<td>9408</td>
<td>18816</td>
<td>37632</td>
<td>75264</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>6.1</td>
<td>12.2</td>
<td>24.4</td>
<td>48.8</td>
<td>97.6</td>
<td>195.3</td>
<td>390.5</td>
<td>781.0</td>
<td>1562</td>
<td>3124</td>
<td>6248</td>
<td>12497</td>
<td>24994</td>
<td>49988</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>7.6</td>
<td>15.2</td>
<td>30.4</td>
<td>60.8</td>
<td>121.6</td>
<td>243.2</td>
<td>486.4</td>
<td>972.8</td>
<td>1945.6</td>
<td>3891.2</td>
<td>7782.4</td>
<td>15564.8</td>
<td>31130.4</td>
<td>62260.8</td>
<td>124521.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>9.1</td>
<td>18.2</td>
<td>36.4</td>
<td>72.8</td>
<td>145.6</td>
<td>291.2</td>
<td>582.4</td>
<td>1164.8</td>
<td>2329.6</td>
<td>4659.2</td>
<td>9318.4</td>
<td>18636.8</td>
<td>37273.6</td>
<td>74547.2</td>
<td>149094.4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### mCi

| GBq  | 108.8 | 135.4 | 162.1 | 202.7 | 216.2 | 270.7 | 324.3 | 351.3 | 405.4 | 459.6 | 500.0 | 540.5 | 621.2 | 675.8 | 810.8 | 945.9 | 1081.8 | 1351.3 | 2216.2 |
|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Day  | 0.5   | 1.0   | 1.7   | 3.4   | 6.8   | 13.6  | 27.2  | 54.4  | 108.8 | 217.6 | 435.2 | 870.4 | 1740.8 | 3481.6 | 6963.2 | 13926.4 | 27852.8 | 55705.6 |
| 2    | 1.0   | 2.0   | 3.4   | 6.8   | 13.6  | 27.2  | 54.4  | 108.8 | 217.6 | 435.2 | 870.4 | 1740.8 | 3481.6 | 6963.2 | 13926.4 | 27852.8 | 55705.6 |
| 3    | 1.5   | 3.0   | 5.2   | 10.4  | 20.8  | 41.6  | 83.2  | 166.4 | 332.8 | 665.6 | 1331.2 | 2662.4 | 5324.8 | 10649.6 | 21300.0 | 42599.9 |
| 4    | 2.0   | 4.0   | 7.2   | 14.4  | 28.8  | 57.6  | 115.2 | 230.4 | 460.8 | 921.6 | 1843.2 | 3686.4 | 7372.8 | 14745.6 | 29491.2 | 58982.4 |
| 5    | 2.5   | 5.0   | 9.0   | 18.0  | 36.0  | 72.0  | 144.0 | 288.0 | 576.0 | 1152.0 | 2304.0 | 4608.0 | 9216.0 | 18432.0 | 36864.0 | 73728.0 |
| 6    | 3.0   | 6.0   | 12.0  | 24.0  | 48.0  | 96.0  | 192.0 | 384.0 | 768.0 | 1536.0 | 3072.0 | 6144.0 | 12288.0 | 24576.0 | 49152.0 | 98304.0 |
| 7    | 3.5   | 7.0   | 14.0  | 28.0  | 56.0  | 112.0 | 224.0 | 448.0 | 896.0 | 1792.0 | 3584.0 | 7168.0 | 14336.0 | 28672.0 | 57344.0 | 114688.0 |
| 8    | 4.0   | 8.0   | 16.0  | 32.0  | 64.0  | 128.0 | 256.0 | 512.0 | 1024.0 | 2048.0 | 4096.0 | 8192.0 | 16384.0 | 32768.0 | 65536.0 | 131072.0 |

---

*Note: The table values are rounded to the nearest whole number.*
Excipients:
Sodium chloride
Water for injection

Indications
This medicinal product is for diagnostic use only. The eluate from the generator (sodium pertechnetate $^{99m}$Tc 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 radioiodine 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.

Technical parameters
Elution time varies from 2 minutes for eluate volume 4.0±0.5 ml, up to 4 minutes for eluate volume 8.0±0.5 ml. Generator is a “dry column” system.

- elution yield: 90 - 110% of nominal activity
- radiochemical purity of the eluate: > 98%
- assay of $^{99m}$Mo in the eluate: < 0.1%
- assay of Al$^{3+}$ in the eluate: < 5 ug/ml
- pH of the eluate: 5.5 - 7.5
- weight of the generator: 16 kg

Posology and method of administration:
If sodium pertechnetate-$^{99m}$Tc is administered intravenously, activities may vary widely according to the clinical information required and the equipment employed. The injection of activities greater than local DRLs (Diagnostic Reference Levels) should be justified for certain indications. The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group.

(for detailed information see SmPC)

Expiration
21 days from manufacturing date. The calibration date and the expiry date are stated on the label.

Sodium pertechnetate-$^{99m}$Tc eluate: after elution, use within 12 hours. This medicinal product does not require any special storage conditions.

Special precautions for storage
Generator: do not freeze.

Marketing Authorization:

<table>
<thead>
<tr>
<th>Country</th>
<th>Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Belarus</td>
<td>Polgentek</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Czech</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Denmark</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Georgia</td>
<td>Polgentec</td>
</tr>
<tr>
<td>Greece</td>
<td>Technegen</td>
</tr>
<tr>
<td>Germany</td>
<td>Pertector</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Poltechgen 8,0-175 GBq, radionuklidų generatorius</td>
</tr>
<tr>
<td>Poland</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Portugal</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Romania</td>
<td>Poltechnet 8,0-175 GBq generator de radionuclizi</td>
</tr>
<tr>
<td>Russia</td>
<td>Polgentek</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Poltechnet 8-175 GBq, radionuklidni generator</td>
</tr>
<tr>
<td>Spain</td>
<td>Poltechnet 8,0-175 GBq generador de radionúclido</td>
</tr>
<tr>
<td>Sweden</td>
<td>Poltechnet</td>
</tr>
<tr>
<td>Ukraine</td>
<td>Poltechnet</td>
</tr>
</tbody>
</table>

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
Accessories for radionuclide generator

**Kit for elution of Poltechnet**

- **Content:**
  - 16 eluent vials of 10 ml volume containing 0.9% aqueous solution of NaCl
  - 16 vacuum vials of 10 ml volume

- **Expiration:**
  12 months

- **Storage:**
  < 25°C

**Kit for aluminium determination**

- **Composition:**
  Indicator strips and reagent for 10 tests

- **Sensitivity:**
  5 µg/ml

- **Expiration:**
  6 months

- **Storage:**
  at room temperature

**Lead shield for eluate vial**

**Kit for aluminium determination**

- **Composition:**
  Indicator strips and reagent for 10 tests

- **Sensitivity:**
  5 µg/ml

- **Expiration:**
  6 months

- **Storage:**
  at room temperature
Syringe shieldings

- Lead shield for 2 cm³ syringe code: OS-2
- Lead shield for 5 cm³ syringe code: OS-5
- Lead shield for 5 cm³ syringe code: OS-5A
- Shielding stand for syringe code: OS-P-10
- Tungsten shield for 2 cm³ syringe code: OSW-2
- Tungsten shield for 3 cm³ syringe code: OSW-3
- Tungsten shield for 5 cm³ syringe code: OSW-5
- Tungsten shield for 10 cm³ syringe code: OSW-10

<table>
<thead>
<tr>
<th>Lead shield code</th>
<th>Length [mm]</th>
<th>Internal diameter [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSW-2</td>
<td>51</td>
<td>10.5</td>
</tr>
<tr>
<td>OSW-3</td>
<td>62</td>
<td>14.2</td>
</tr>
<tr>
<td>OSW-5A</td>
<td>62</td>
<td>15.2</td>
</tr>
<tr>
<td>OSW-10</td>
<td>160</td>
<td>19.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tungsten shield code</th>
<th>Length [mm]</th>
<th>Internal diameter [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSW-2</td>
<td>50</td>
<td>10.3 (11.0)*</td>
</tr>
<tr>
<td>OSW-3</td>
<td>52</td>
<td>11.0 (11.4)*</td>
</tr>
<tr>
<td>OSW-5</td>
<td>60</td>
<td>14.0 (15.0)*</td>
</tr>
<tr>
<td>OSW-10</td>
<td>71</td>
<td>18.0</td>
</tr>
</tbody>
</table>

* enlarged internal diameter for the first 7-9 mm section in order to adapt to the shape of different syringes
**PoltechColloid, 0.17 mg**

**Kit for radiopharmaceutical preparation**

*Stanni colloidalis et technetii (⁹⁹ᵐTc) solutio injectabilis*  

**code: MTcK-2**

- **Qualitative and quantitative composition:**  
  Stannous chloride dihydrate 0.17 mg

- **Excipients:**  
  Sodium fluoride, povidone, nitrogen

- **Indications:**  
  This medicinal product is for diagnostic use only. Technetium-⁹⁹ᵐ colloidal tin injection is used for scintigraphic diagnostics of reticuloendothelial system of liver and spleen.

- **Posology and method of administration:**  
  The solution of the radiopharmaceutical ⁹⁹ᵐTc-Colloid, obtained by reconstitution of lyophilisate in 5 ml of sterile, bacterial endotoxins and oxidant free eluate from a radionuclide generator ⁹⁹ᵐMo/⁹⁹ᵐTc with activity of 100-1000 MBq in accordance with the labelling instructions.

  One vial of the product labelled with ⁹⁹ᵐTc may be used for examinations of several patients.

  There is no special requirements for patient preparation.

  The activity recommended for examination of a single adult patient ranges from 150 to 200 MBq of ⁹⁹ᵐTc-Colloid, however depending on indications other doses may be justifiable.

  For elderly population literature data does not indicate the need for dosage adjustment.

  The use of the product in paediatric patients has to be considered carefully, based upon clinical needs and assessment of the risk/benefit ratio in this patient group. The activity for children may be calculated by modifying the adult activity according to body weight or body surface of the child.

  *(for detailed information see SmPC)*

- **Stability:**  
  4 hours after completion of labelling procedure, below 25°C

- **Expiration:**  
  the shelf life of the kit is one year from the day of manufacture

- **Storage:**  
  at temperature from 2°C to 8°C

- **Package:**  
  3 or 6 vials in the cardboard box

---

**Marketing authorization:**  
Poland, Belarus

**Contact:**  
Export Department +48 22 273 1820  
email: export@polatom.pl
PoltechDMSA, 1 mg
Kit for radiopharmaceutical preparation
Technetii (99mTc)succimeri solutio inyectabilis
code: MTcK-12

- Qualitative and quantitative composition:
  meso-2,3-dimercaptosuccinic acid (DMSA) 1 mg

- Excipients:
  Stannous chloride dihydrate, ascorbic acid, d-mannitol, nitrogen

- Indications:
  PoltechDMSA is intended for renal scintigraphic examination, static renal imaging, location of kidneys, determination of functional renal mass, determination of relative individual kidney function. After intravenous administration it exhibits a strong affinity for renal cortex.

- Posology and method of administration:
  PoltechDMSA is administered intravenously after labelling with sterile, oxidant-free eluate from a radionuclide generator 99Mo/99mTc, in accordance with the labelling instructions.

  The recommended activity for examination of a single adult patient ranges from 75 to 150 MBq.

  Technetium-99m in 5 ml of eluate of sodium pertechnetate,99mTc (eluate from a radionuclide generator 99Mo/99mTc) with activity of 100-7400 MBq may be used for labelling of one kit vial.

  This amount is sufficient to perform the examination in several adult patients.

  99mTc-DMSA renal concentration increases gradually within 6-8 hours after injection. The kidneys accumulate about 45-60% of the administered dose. Blood radioactivity decreases in a constant manner: by 20-39 % after 10 minutes, about 2% of the dose retains in the blood after 24 hours.

  There is no data on safety and efficacy of the radiopharmaceutical used in children under 18 years of age

  (for detailed information see SmPC)

- Stability:
  4 hours after completion of labelling procedure, below 25ºC

- Expiration:
  the shelf life of the kit is 6 months from the day of manufacture

- Storage:
  at temperature from 2ºC to 8ºC

- Package:
  3 or 6 vials in the cardboard box

Marketing authorization:
Poland, Belarus, Colombia

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
PoltechDTPA, 13.25 mg

Kit for radiopharmaceutical preparation

Technetii ($^{99m}$Tc) pentetatis solutio injectabilis

code: MTcK-4

- **Qualitative and quantitative composition:**
  sodium diethylenetriaminepentaacetate monohydrate (DTPA) 13.25 mg

- **Excipients:**
  Stannous chloride dihydrate, sodium chloride, nitrogen

- **Indications:**
  The kit for the preparation of $^{99m}$Tc-DTPA is intended for:
  - renal scintigraphic imaging (dynamic renal scintigraphy for GFR measurement of each kidney, evaluation of urinary flow disorders)
  - the cerebral angiography and brain scanning.

- **Posology and method of administration:**
  The radiopharmaceutical $^{99m}$Tc-DTPA is administered intravenously after labelling with sterile, oxidant-free eluate from a radionuclide generator $^{99}$Mo/$^{99m}$Tc in accordance with the labelling instructions.

  The activity recommended for examination of a single adult patient ranges from 74 to 370 MBq for kidneys examination and 370-555 MBq for brain examination.

  Technetium-99m in 5 ml of eluate of sodium pertechnetate-$^{99m}$Tc (eluate from a radionuclide generator $^{99}$Mo/$^{99m}$Tc) with activity of 740-1500 MBq may be used for labelling of one kit vial.

  This amount is sufficient to perform the examination in several adult patients.

  There are no data on safety and efficacy of the radiopharmaceutical in children under 18 years of age.

  *(for detailed information see SmPC)*

- **Stability:**
  6 hours after completion of labelling procedure, below 25°C

- **Expiration:**
  the shelf life of the kit is one year from the day of manufacture

- **Storage:**
  at temperature from 2°C to 8°C

- **Package:**
  3 or 6 vials in the cardboard box

---

Marketing authorization:
Poland, Belarus

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
**PoltechMBrIDA, 20 mg**

**Kit for radiopharmaceutical preparation**

*Technetii (99mTc) mebrofenini solutio injectabilis*  

code: MTcK-16

**Qualitative and quantitative composition:**  
N-[2,4,6-trimethyl-3-bromacetanilid]iminodiacetic acid sodium salt 20 mg

**Excipients:**  
Stannous chloride dihydrate, nitrogen

**Indications:**  
The radiopharmaceutical 99mTc-MBrIDA is indicated for diagnostics of:  
- hepatobiliary tract patency and for differentiation of jaundice. It is used for imaging of hepatobiliary system, especially at reduced hepatic function and high bilirubin levels. Cholescintigraphy may be performed even at serum bilirubin levels higher than 5 mg%.  
- hepatitis, hepatic duct occlusion, gallbladder functional disorders, inflammation of the hepatobiliary system, cholecystitis with occlusion of the cystic duct and other hepatic and hepatobiliary system pathologies.  
- for detection of intrahepatic cholestasis in order to differentiate it from other hepatobiliary diseases, which involve hepatocyte damage.

**Posology and method of administration:**  
The radiopharmaceutical 99mTc-MBrIDA is administered intravenously after labelling with sterile, oxidant free eluate from radionuclide generator 99Mo/99mTc in accordance with the labelling instructions.

Eluate of sodium pertechnetate-99mTc solution (eluate from radionuclide generator 99mMo/99mTc) with technetium-99m activity of 370-1500 MBq in 5ml volume can be used for labeling of one kit vial.

This quantity allows to carry out the examination in several (1-10) adult patients.

In very small children (up to 1 year) a minimum dose of 20 MBq is recommended in order to obtain images of sufficient quality.  
*(for detailed information see SmPC)*

**Stability:**  
5 hours after completion of labelling procedure, below 25°C

**Expiration:**  
the shelf life of the kit is one year from the day of manufacture

**Storage:**  
at temperature from 2°C to 8°C

**Package:**  
3 or 6 vials in the cardboard box

---

Marketing authorization:  
Poland, Belarus, Colombia

Contact:  
Export Department +48 22 273 1820  
email: export@polatom.pl
PoltechMDP, 5 mg

Kit for radiopharmaceutical preparation

Technetii ($^{99m}$Tc) medronas solutio inyectabilis
code: MTcK-8

- **Qualitative and quantitative composition:**
  Methyleneephosphonic acid 5 mg (as the sodium salt 6.25 mg)

- **Excipients:**
  Stannous chloride, ascorbic acid, nitrogen

- **Indications:**
  The radiopharmaceutical $^{99m}$Tc-MDP is intended for skeletal imaging utilizing radioactive properties of technetium-99m and the affinity of methylenephosphonic acid to hydroxyapatite crystals which form inorganic structure of bone tissue.

  Indications for scintigraphic examinations using $^{99m}$Tc-MDP are as follows:
  - detection of metastatic foci in skeletal system;
  - imaging of altered bone metabolism in primary bone tumors;
  - imaging of bone inflammation;
  - imaging of post-traumatic lesions;
  - imaging of rheumatoid lesions;
  - imaging of aseptic necrosis;
  - diagnosis of soft tissue diseases, eg. myositis ossificans;
  - examination of repair processes in damaged bone tissue.

  Use of the radiopharmaceutical for the aforementioned purposes enables precise localization and assessment of lesions extent.

- **Posology and method of administration:**
  The radiopharmaceutical $^{99m}$Tc-MDP is administered intravenously after labelling with sterile, oxidant-free eluate from a radionuclide generator $^{99}$Mo/$^{99m}$Tc, in accordance with the labelling instructions.

  Eluate of sodium pertechnetate-$^{99m}$Tc solution (eluate from a radionuclide generator $^{99}$Mo/$^{99m}$Tc) with $^{99m}$Tc activity of 1100-18500 MBq may be used for labelling of one kit vial. The activity recommended for a single examination of skeletal system in adult patient in the ranges from 370 to 740 MBq.

  Basically, there are three methods of skeletal scintigraphy: planar technique, SPECT (single photon emission computed tomography) and three phase bone scintigraphy.

  High quality scintigraphy images (e.g. in three phase scintigraphy) are obtained by using the so-called late phase static scintigraphy, i.e. by performing the examination not earlier than 2 hours after intravenous administration of radiopharmaceutical. The earlier acquisition may result in images which only partly reflect the metabolic activity of the bones.

  Slow administration of the preparation over a period of around 30 seconds is recommended. The radioactivity to be administered to a child should be determined with Webster’s formula.

  In very small children (up to 1 year) a minimum dose of 40 MBq is recommended in order to obtain images of sufficient quality.

  *(for detailed information see SmPC)*

- **Stability:**
  8 hours after completion of labelling procedure, below 25°C

- **Expiration:**
  the shelf life of the kit is one year from the day of manufacture

- **Storage:**
  at temperature from 2°C to 8°C

- **Package:**
  3 or 6 vials in the cardboard box

Marketing authorization:
Poland, Belarus, Georgia, Greece

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
PoltechMIBI, 1 mg
Kit for radiopharmaceutical preparation

Technetii (99mTc) sestamibi solutio injectabilis
code: MTcK-7

- Qualitative and quantitative composition:
  [Tetrakis(2-methoxy-2-methylpropyl-1-isocyanide) copper(1+)]tetrafluoroborate 1 mg

- Excipients:
  Stannous chloride dihydrate, l-cysteine hydrochloride monohydrate, sodium citrate dihydrate, d-mannitol

- Indications:
  For intravenous injection after radiolabelling with sodium pertechnetate-99mTc solution. PoltechMIBI using scintigraphy is indicated for:
  - diagnosis of ischaemic heart disease;
  - diagnosis and localisation of myocardial infarction;
  - assessment of global ventricular function (first pass technique for determination of ejection fraction and/or regional wall motion),
  - diagnosis of malignancy in patients who are suspected of cancer in the breast combined with inconclusive mammography or palpable tumour and negative or inconclusive mammography,
  - diagnosis of patients with recurrent or persistent hyperparathyroidism.

- Posology and method of administration:
  This medicinal product is administered intravenously and should be reconstituted before administration to the patient. The vial is reconstituted with a maximum of 11 GBq of oxidant-free sodium pertechnetate-99mTc solution for injection in 1-5 ml.
  Not less than 5 ml will be used for the highest activity of 11 GBq. Radiochemical purity should be checked prior to patient administration.
  The use of PoltechMIBI in paediatric patients has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. Safety and efficacy in children and adolescents below the age of 18 have not been fully established.

  (for detailed information see SmPC)

- Stability:
  12 hours after completion of labelling procedure, below 25°C

- Expiration:
  the shelf life of the kit is one year from the day of manufacture

- Storage:
  at temperature from 2°C to 8°C

- Package:
  3 or 6 vials in the cardboard box

Marketing authorization:

Austria: CardioTOP
Belarus: НАБОР ДЛЯ ПОЛУЧЕНИЯ КОМПЛЕКСА 99mTc-MIBI
Colombia: MIBI
France: CARDIOMIBI
Georgia: Kit for preparation of radiopharmaceutical 99mTc-MIBI
Germany: CardioTOP
Greece: Cardioscan
India: MIBI KIT FOR THE LABELING BY TC 99M
Italy: MIBISPECT
Poland: PoltechMIBI
Spain: MIBI INSTITUTE OF ATOMIC ENERGY
Turkey: Tc-99m - MIBI
United Kingdom: CARDIOVIS

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
PoltechRBC, 13.40 mg

Kit for radiopharmaceutical preparation

*Stanni pyrophosphatis et technetii (99mTc) solutio inyectabilis*  
code: MTcK-5

- **Qualitative and quantitative composition:**  
  Sodium pyrophosphate decahydrate 13.40 mg

- **Excipients:**  
  Stannous (II) chloride dihydrate 4.3 mg, nitrogen

- **Indications:**  
  This medicinal product is indicated for *In vivo, in vitro* or *in vivo/in vitro* red blood cell labelling for blood pool scintigraphy used for:
  - evaluation of ventricular ejection fraction,
  - evaluation of global and regional cardiac wall motion,
  - phase analysis of myocardial contractility.
  - organ perfusion and vascular abnormalities imaging.
  - diagnosis and localization of occult gastrointestinal bleeding.
  - determination of blood volume,
  - spleen scintigraphy.

- **Posology and method of administration:**  
  Before administration to the patient, this medicinal product should be reconstituted with isotonic sodium chloride solution for injection.
  For diagnostic scintigraphy based on labelled erythrocytes, complex of pyrophosphate with tin (II) is prepared by dissolving lyophilisate in normal saline.

**Red blood cells labelling methods**

- **In vivo method**  
  Inject intravenously appropriate volume of solution prepared by dissolving contents of the vial in normal saline in order to introduce stannous ions into erythrocytes *in vivo*. Subsequently collect a sample of blood from the patient and label *in vitro* with sodium pertechnetate-99mTc. Inject labelled erythrocytes into the patient.

- **In vitro method**  
  Collect a sample of blood from the patient. Incubate *in vitro* the blood sample or isolated erythrocytes with appropriate volume of solution prepared by dissolving contents of the vial in normal saline, add sterile solution of sodium pertechnetate-99mTc and inject labelled erythrocytes into the patient.

- **Labelling of denatured erythrocytes**  
  Label erythrocytes *in vitro*, then denature them e.g. by heating at 49–50°C for 25 minutes. Inject labelled, denatured erythrocytes into the patient.

The use of the product in paediatric patients has to be considered carefully, based upon clinical needs and assessment of the risk/benefit ratio in this patient group.

*(for detailed information see SmPC)*

- **Stability:**  
  3 hours after completion of labelling procedure, below 25°C

- **Expiration:**  
  the shelf life of the kit is one year from the day of manufacture

- **Storage:**  
  at temperature from 2°C to 8°C

- **Package:**  
  3 or 6 vials in the cardboard box

Marketing authorization in Poland

Contact:  
Export Department +48 22 273 1820  
email: export@polatom.pl
Techimmuna, 2 mg
Kit for radiopharmaceutical preparation

Human immunoglobulin G (modified)

Qualitative and quantitative composition:
Human immunoglobulin G (modified), 2 mg
Human immunoglobulin G is a polyclonal antibody, obtained by the fractionation of plasma proteins using Cohn alcohol method. To allow binding with radionuclide technetium-99m, human immunoglobulin G is derivatised by reaction with hydrazinonicotinic acid (HYNIC).

Excipients:
Vial I: Sodium citrate dihydrate, citric acid monohydrate
Vial II: Stannous chloride dehydrate, tricine
PBS: Sodium chloride, potassium chloride, disodium hydrogen phosphate, potassium dihydrogen phosphate

Indications:
This medicinal product is for diagnostic use only. Human immunoglobulin G labelled with radionuclide technetium-99m, is used for detection and localization of inflammatory lesions. The product can also be used for semi-quantitative assessment of inflammatory activity, in particular in rheumatoid arthritis.

Posology and method of administration:
Techimmuna is administered intravenously in a single dose after labelling of the kit using a sterile, oxidant-free sodium pertechnetate-\(^{99m}\)Tc solution for injection (eluate of \(^{99m}\)Mo/\(^{99m}\)Tc radionuclide generator).

The suggested activity is the range of 555-740 MBq. Radioactivity of administered dose should be always adjusted with respect to its diagnostic usefulness.

The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk and benefit ratio in this patient group.

The activity to be administered to children is lower and follows methods of activity calculation.

(For detailed information see SmPC)

Stability:
3 hours after completion of labelling procedure at temperature below 25°C. In transport (up to 2 hours) the acceptable temperature is below 35°C.

Expiration:
Kit shelf life: 9 months

Storage:
at temperature from 2°C to 8°C

Package:
The kit package contains two glass vials (Vial I and Vial II) of 10 ml volume, closed with rubber stopper and aluminium crimp cap. The vials are supplied in cardboard boxes. Vials I and II contain components for preparation of radiopharmaceutical Techimmuna.

Marketing authorization in Poland

Contact:
Export Department +48 22 273 1820
e-mail: export@polatom.pl
**99mTc-Tektrotyd, 16 micrograms**

**Kit for radiopharmaceutical preparation**

99mTc-HYNIC-Tyr³-Octreotide
code: MTcK-20

- Qualitative and quantitative composition:
  HYNIC-[D-Phe¹,Tyr³-Octreotide]-TFA, 16 micrograms

- Excipients:
  
  Vial I: Tricine (N-[Tris(hydroxymethyl)methyl] glycine), tin (II) chloride dihydrate, mannitol, nitrogen

  Vial II: EDDA (ethylenediamine-N,N’-diacetic acid), disodium hydrogen phosphate dodecahydrate, sodium hydroxide, nitrogen

- Indications:
  99mTc-Tektrotyd is a radiopharmaceutical indicated for diagnostics of pathological lesions in which somatostatin receptors are overexpressed (particularly subtype 2 and, to a lesser extent, subtypes 3 and 5) and which may be imaged by the labelled ligand.

  In particular, these are:

  ► gastro-entero-pancreatic neuroendocrine tumours (GEP-NET),

  ► pituitary adenomas,

  ► tumours originating in a sympathetic system; pheochromocytoma, paraganglioma, neuroblastoma, ganglioneuroma etc.,

  ► medullary thyroid carcinoma,

  ► the preparation may be potentially useful in the case of other tumours expressing somatostatin receptors of various intensity and other tumours which may overexpress somatostatin receptors: breast cancer, melanoma, lymphomas, prostate cancer, NSCLC, sarcoma, renal cell carcinoma, differentiated thyroid carcinoma, astrocytoma according to WHO I-IV (including glioblastoma multiforme G-M), meningiomas, ovarian cancer.

- Posology and method of administration:
  99mTc-Tektrotyd is administered intravenously in a single dose after labelling of the kit using a sterile, oxidant-free sodium pertechnetate-99mTc solution for injection (eluate of 99Mo/99mTc radionuclide generator) in accordance with the instructions for preparation of radiopharmaceutical. 99mTc in 1 ml of eluate of sodium pertechnetate-99mTc solution for injection with activity of 740 - 1200 MBq (maximally 2200 MBq) may be used for labelling of one kit. This activity is sufficient for examinations of 1–2 adults. The solution of 99mTc-Tektrotyd may be additionally diluted for more convenient administration. Acquisition should be carried out between 2–4 hours after intravenous administration of the preparation. The examination may be complemented by acquisition after 10 minutes, 1 hour and 24 hours after administration of the tracer. It is recommended to carry out the examinations using Whole Body technique and SPECT of selected body areas.

  99mTc-Tektrotyd is not recommended for use in patients under 18 years of age; there are no data for this age group.

  99mTc-Tektrotyd is intended for a single intravenous use only. If there is a need for repeated administration, clinical indication and potential adverse events should be considered.

  (for detailed information see SmPC)

- Stability:
  6 hours after completion of labelling procedure, below 25ºC

- Expiration:
  the shelf life of the kit is one year from the day of manufacture

- Storage:
  at temperature from 2ºC to 8ºC

- Package:
  1 set of 2 vials in the cardboard box

---

Marketing authorization:
Poland, Colombia, Greece

Pending in: Austria, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Norway, Portugal, Romania, Sweden, Spain, Slovakia, United Kingdom

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
**Hippurate-\(^{131}\)I**

*for injection*

*Natrii iodohippurati (\(^{131}\)I) solutio injectabilis*  

code: MI-18

- **Qualitative and quantitative composition:**  
  Sodium 2-[\(^{131}\)I]iodohippurate 3.7-74 MBq/ml

- **Excipients:**  
  Benzyl alcohol, sodium chloride, water for injection

- **Indications:**  
  Hippurate-\(^{131}\)I is a radiopharmaceutical used in diagnostics of kidneys dysfunction and urinary tract obstructions (dynamic renal scintigraphy, renoscintigraphy). Renal scintigraphy utilizing this radiopharmaceutical allows the evaluation of:  
  - kidney blood flow resolution (effective renal plasma flow – ERPF),  
  - renal tubular function,  
  - urine outflow from the pyelocalyceal system,  
  - vesico-ureteral reflux (examination during miction),  
  - renal function impairment in transplanted kidney and can be used in the diagnostics of renovascular hypertension (particularly in the captopril enhanced renal scintigraphy). The preparation accumulates in the kidneys where it concentrates and is later excreted.

- **Posology and method of administration:**  
  Hippurate-\(^{131}\)I for injection is administered in a single dose corresponding to activity of 0.185-1.295 MBq for adult patient (70 kg). Depending on the diagnostic indication, the administration is by intravenous infusion or injection. After intravenous administration, Hippurate-\(^{131}\)I for injection accumulates over 2-5 minutes in the kidneys, where it is concentrated and then excreted.

*(for detailed information see SmPC)*

- **Calibration:**  
  7 days

- **Radionuclidic purity:**  
  \(\geq 99.9\%\)

- **Radiochemical purity:**  
  \(\geq 96\%\)

- **Expiration:**  
  21 days from the production date

- **Storage:**  
  at temperature from 2°C to 8°C

- **Package:**  
  10 ml glass vials, closed with rubber stoppers and aluminum caps and placed inside a lead container.

**Marketing authorization:**  
Poland, Belarus, Ukraine

**Contact:**  
Export Department +48 22 273 1820  
email: export@polatom.pl
MIBG-\textsuperscript{131}I Meta-Iodobenzylguanidine-\textsuperscript{131}I for diagnostic use, solution for injection
\textit{Iobenguani (\textsuperscript{131}I) solutio injectabilis ad usum diagnosticum} code: MI-10D

- **Qualitative and quantitative composition:** Meta-iodo\textsuperscript{131}I benzylguanidine sulphate, 10-37 MBq/ml

- **Excipients:**
  - Meta-iodobenzylguanidine sulphate, sodium metabisulphite, copper (II) sulphate pentahydrate, sodium acetate trihydrate, acetic acid, benzyl alcohol, sodium chloride, water for injection

- **Indications:**
  - MIBG-\textsuperscript{131}I (MIBG-\textsuperscript{131}I) is a diagnostic radiopharmaceutical for gamma-szintigraphy. It is indicated for use:
    - in the detection and localization of primary or metastatic pheochromocytoma in adrenals and out of the adrenals, neuroblastoma, paraganglioma, imaging of neuroendocrine tumors of gastroenteropancreatic tract, medullary thyroid carcinoma
    - in the cardiac diagnostics in diseases resulting from myocardial ischemia and cardiomiopathy.

- **Posology and method of administration:**
  - The posology depends on the type of examination. In diagnostic examinations, the radiopharmaceutical is slowly administered intravenously (over approximately 30 seconds). In scintigraphic imaging of pheochromocytoma, the recommended dose for adults is 18.5-37 MBq. The scintigraphic examination should be performed after 24, 48 and 72 hours after administration of the radiopharmaceutical. As a method facilitating the interpretation of the scintigraphic image, it is recommended that the MIBG-\textsuperscript{131}I image is superimposed on the image of kidneys, obtained after administering \textsuperscript{99m}Tc-DTPA, or an image of the skeleton, obtained after administering \textsuperscript{99m}Tc-MDP. Since the pheochromocytoma can be found outside of the kidneys in 10-15% of all cases, it is recommended to perform the whole body scan.

  \textit{(for detailed information see SmPC)}

- **Calibration:** 9 days from the production date

- **Radionuclidic purity:** \( \geq 99.9\% \)

- **Radiochemical purity:** \( \geq 94\% \)

- **Expiration:** 9 days from the production date

- **Storage:** at temperature below \([-15^\circ C]\). Protect from light. After defrosting 4 hours below 25\(^\circ\)C. Transportation should be carried in dry ice.

- **Package:** MIBG-\textsuperscript{131}I solution is delivered in 10 ml glass vials, with a possibility of drawing multidoses in an aseptic way. The vials are capped with rubber stoppers and aluminum caps and placed inside a lead shielding container. The outer transport packaging is a metal tin with styrofoam insert.

---

**Marketing authorization in Poland**

**Contact:**
Export Department +48 22 273 1820  
email:  export@polatom.pl
MIBG-\textsuperscript{131}I Meta-Iodobenzylguanidine-\textsuperscript{131}I
for therapeutic use, solution for injection
\textit{Iobenguani (\textsuperscript{131}I) solutio injectabilis ad usum therapeuticum}

- **Qualitative and quantitative composition:**
  Meta-Iodo\textsuperscript{131}I benzylguanidine sulphate, 370-740 MBq/ml

- **Excipients:**
  Sodium metabisulphite, copper (II) sulphate pentahydrate, sodium acetate trihydrate, acetic acid, benzyl alcohol, sodium chloride, water for injection

- **Indications:**
  Meta-Iodobenzylguanidine-\textsuperscript{131}I (MIBG-\textsuperscript{131}I) is a radiopharmaceutical used in cancer therapy. It is used in treating disseminated, malignant, metastatic lesions, such as pheochromocytoma, para-ganglioma, neuroblastoma, neuroendocrine tumors of gastroenteropancreatic tract, and sometimes medullary thyroid carcinoma.

- **Posology and method of administration:**
  In cancer therapy using the MIBG-\textsuperscript{131}I the recommended single dose is approximately 3.7 GBq.

  The therapeutic dose should be diluted with saline to a volume of approximately 50 ml and administered intravenously within 1½-2 hours.

  The recommended dose is the same for adults and children.

  Before administration MIBG-\textsuperscript{131}I it is necessary to block the thyroid. This can be done via the administration of iodine solutions, such as the Lugol’s solution, in amounts equivalent to 40 mg of iodine per day, for 7 days, starting 3 days before administering the radiopharmaceutical, and for three days following the administration. Potassium perchlorate may also be used for blocking the thyroid.

  (for detailed information see SmPC)

- **Calibration:**
  24 or 48 or 72 hours from the production date

- **Radiochemical purity:**
  \( \geq 92\% \)

- **Expiration:**
  4 days from the production date

- **Storage:**
  at temperature below [-15\(^\circ\)C]. Protect from light. After defrosting 2 hours below 25\(^\circ\)C. Transportation should be carried in dry ice.

- **Package:**
  MIBG-\textsuperscript{131}I solution is delivered in 10 ml glass vials, with a possibility of drawing multidoses in an aseptic way. The vials are capped with rubber stoppers and aluminum caps and placed inside a lead shielding container. The outer transport packaging is a metal tin with styrofoam insert.

- Marketing authorization in Poland

  Contact:
  Export Department +48 22 273 1820
  email: export@polatom.pl
MIBG-^{123}\text{I} Meta-Iodobenzylguanidine-^{123}\text{I} solution for injection

lobenguani (^{123}\text{I}) solutio injectabilis

code: MI-23

- **Qualitative and quantitative composition:**
  Meta-iodo^{[123]}\text{I} benzylguanidine sulphate, 18.5 - 370 MBq/ml

- **Excipients:**
  Sodium metabisulphite, copper (II) sulphate pentahydrate, sodium acetate trihydrate, acetic acid, benzyl alcohol, sodium chloride, water for injections

- **Indications:**
  Metaiodobenzylguanidine^{123}\text{I} (MIBG-^{123}\text{I}) is a radiopharmaceutical product used in scintigraphic detection and treatment monitoring of primary or metastatic pheochromocytoma or neuroblastoma.
  The use of MIBG-^{123}\text{I} labelled radiopharmaceutical product is particularly recommended in children diagnosis.

- **Posology and method of administration:**
  This radiopharmaceutical product is administered by slow intravenous injection (over 2 minutes).
  MIBG^{123}\text{I} dose depends on patient age and weight.
  The recommended dose for 20 kg child is 74 MBq.
  Adults: the recommended dose is in the range of 37-185 MBq.
  Scintigraphy should be taken between 6 and 24 hours after MIBG-^{123}\text{I} administration.

  *(for detailed information see SmPC)*

- **Calibration:**
  at 10 am on next day after production

- **Radionuclidian purity:**
  $> 99.65\%$

- **Radiochemical purity:**
  $\geq 95\%$

- **Expiration:**
  30 hours after the hour and date of manufacturing (expiry date is given on the packaging)

- **Storage:**
  MIBG-^{123}\text{I} should be stored at room temperature, in radiation shielding for ensuring the safety, in accordance with local regulations.

- **Package:**
  MIBG-^{123}\text{I} solution is delivered in 10 ml glass vials, with a possibility of drawing multidoses in an aseptic way. The vials are capped with rubber stoppers and aluminum caps and placed inside a lead shielding container. The outer transport packaging is a metal tin with styrofoam insert.

---

Marketing authorization in Poland

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
Na\textsubscript{2}H\textsuperscript{32}PO\textsubscript{4} sodium orthophosphate

solution for injection

*Natrii phosphatis (\textsuperscript{32}P) solutio injectabilis*

code: MP-9

- **Qualitative and quantitative composition:**
  Na\textsubscript{2}H\textsuperscript{32}PO\textsubscript{4} sodium orthophosphate, 37-370 MBq/ml

- **Excipients:**
  Disodium hydrophosphate dodecahydrate, sodium chloride, water for injections

- **Indications:**
  Na\textsubscript{2}H\textsuperscript{32}PO\textsubscript{4} sodium orthophosphate injection solution is a radiopharmaceutical intended for:
  - treatment of primary polycythemia and primary polythrombocythemia when all alternative forms of treatment fail to produce results.
  - treatment of leukemia and other hematologic diseases.
  \textsuperscript{32}P-sodium orthophosphate can also be used as a painkiller in bone metastases, but in such cases its toxicity for the bone marrow should be taken into consideration.

- **Posology and method of administration:**
  Na\textsubscript{2}H\textsuperscript{32}PO\textsubscript{4} sodium orthophosphate injection solution is intended for intravenous administration, in various activities, dependant on the treatment being administered.

  - The recommended dose for primary polycythemia treatment is 74-111 MBq per every square meter of body area, but no more than 185 MBq. Another method consists in the administration of a first dose of 111 MBq and a 25% larger one after 3 months, if the patient shows no signs of improvement. A single dose should never exceed 250 MBq.
  - In leukemia, a weekly dose of 37-74 MBq is administered, until the white blood cell count is reduced to a desirable level.
  - In the treatment of bone metastases, a dose of 370-555 MBq may be administered as an analgesic, in 3-4-month intervals, if all alternative forms of treatment, such as hormone treatment chemotherapy and radiotherapy fail to produce satisfactory results. Pain relief after \textsuperscript{32}P therapy may occur within several weeks following the administration of the radiopharmaceutical, its symptoms including an improved mood and reduced need for analgesics.

  *(for detailed information see SmPC)*

- **Calibration:**
  7 days

- **Radionuclidic purity:**
  \( \geq 97\% \)

- **Radiochemical purity:**
  \( \geq 95\% \)

- **Expiration:**
  21 days from the production date

- **Storage:**
  at temperature below 25\(^\circ\)C

- **Package:**
  10 ml glass vials, closed with rubber stoppers and aluminum caps and placed inside a lead container.

---

Marketing authorization:
Poland, Belarus

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
Sodium iodide Na\textsuperscript{131}I POLATOM capsules for diagnostic use. Hard capsules, 1–37 MBq

\textit{Natrii iodidi (\textsuperscript{131}I) capsulae ad usum diagnosticum} code: MI- 4D

- **Qualitative and quantitative composition:** Sodium iodide (Na\textsuperscript{131}I) [1-37 MBq]

- **Excipients:** Sodium carbonate, sodium bicarbonate, disodium hydrogen phosphate dihydrate, sodium thiosulphate pentahydrate, hard gelatin capsule.

- **Indications:**
  - This product is used in diagnostics of:
    - thyroid function disorders (hyperthyroidism and hypothyroidism), evaluation of thyroid tissue location (including ectopy), its size, shape, functional analysis of focal lesions: “cold” (not trapping iodine), “warm” (trapping iodine at a similar extent to normal thyroid parenchyma), “hot” (trapping iodine at a higher extent than normal thyroid parenchyma) nodules.
  - It is the basic radioisotope in the diagnosis of metastatic lesions of differentiated thyroid cancers (following the surgical removal of the thyroid or radioisotope ablation).

- **Posology and method of administration:**
  - Sodium iodide Na\textsuperscript{131}I POLATOM, capsules for diagnostic use, is a preparation for oral administration. In diagnostics, the oral administration of 1-4 MBq of sodium iodide (Na\textsuperscript{131}I) is recommended 24 hours prior to the scintigraphic examination of the thyroid.
  - The activity of the radiopharmaceutical administered to patients should always be considered in relation to its diagnostic value.

  \textit{(for detailed information see SmPC)}

- **Storage:**
  - at temperature below 25°C

- **Package:**
  - Sodium iodide Na\textsuperscript{131}I POLATOM, capsules for diagnostic use, are supplied in two types of immediate packages.
  - \textbf{First type of container:}
    - The capsules with activity of 1-4 MBq are supplied in the polypropylene vials, sealed with the polyethylene stoppers. Vials are placed in the shielding lead containers. A single vial can contain up to 10 capsules of the same radioactivity.
  - \textbf{Second type of container:}
    - The capsules, with activity of 1-37 MBq are supplied in the polypropylene vials, sealed with stopper containing iodine absorber and placed in shielding lead containers. Every vial contains a single capsule. Each container is accompanied by a separate applicator for capsule administration.

- **Calibration:**
  - 7 days

- **Radionuclidic purity:**
  - ≥ 99.9%

- **Radiochemical purity:**
  - ≥ 95%

- **Expiration:**
  - 21 days from the production date

Marketing authorization:
Poland, Belarus, Colombia

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
Sodium iodide Na\textsuperscript{131}I POLATOM
capsules for therapeutic use. Hard capsules, 37–5500 MBq
\textit{Natrii iodidi (\textsuperscript{131}I) capsulae ad usum therapeuticum} code: MI-4T

- **Qualitative and quantitative composition:** Single hard capsule contains sodium iodide (\textsuperscript{131}I) in the radioactivity range [37–5500 MBq]. Iodine-131 is obtained by neutron irradiation of tellurium in a nuclear reactor or by extraction from uranium fission products. Iodine-131 has a half-life of 8.02 days. It decays to stable xenon-131, by emission of gamma radiations of 365 keV (81.7%), 637 keV (7.2%) and 284 keV (6.1%) and beta radiation of maximal energy of 606 keV.

- **Excipients:** Sodium carbonate, sodium hydrogen carbonate, disodium hydrophosphate dehydrate, sodium thiosulphate pentahydrate, hard gelatin capsule.

- **Indications:**
  - This product is used in the treatment of:
    - thyroid nodular goitre, hyperthyroidism in the Graves-Basedow’s disease, autonomic nodule and the toxic multinodular goitre. It is used for the thyroid residue ablation after surgery of differentiated thyroid tumours and in the treatment of iodine-accumulating metastases.

- **Posology and method of administration:** Sodium iodide Na\textsuperscript{131}I POLATOM, capsules for therapeutic use is a medicinal product with varying radioactivity, for oral administration. The recommended therapeutic dose is a matter for clinical judgement. This dose should be established individually for each patient.

  (for detailed information see SmPC)

- **Calibration:**
  - 7 days

- **Radionuclidic purity:**
  - ≥ 99.9%

- **Radiochemical purity:**
  - ≥ 95%

- **Expiration:**
  - 21 days from the production date

- **Storage:**
  - at temperature below 25°C

- **Package:** The polypropylene vial closed with a polypropylene stopper containing iodine absorber and placed in a shielding lead container. Every vial contains a single capsule. Each container is accompanied by a separate polypropylene applicator for capsule administration.

Marketing authorization:
Poland, Belarus, Colombia, South Korea

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
Sodium iodide Na\(^{131}\)I
solution for injection
*Natrii Iodidi (\(^{131}\)I) solutio injectabilis*
code: MI-2

- **Qualitative and quantitative composition:**
  Sodium iodide (Na\(^{131}\)I) [37-740 MBq/ml]

- **Excipients:**
  Sodium carbonate, sodium bicarbonate, sodium thiosulphate pentahydrate, sodium chloride, water for injection

- **Indications:**
  This medicinal product is used:
  - for diagnostic procedures of thyroid function (hyperthyroidism and hypothyroidism), to determine the localisation of thyroid tissue (including ectopy), its size, shape, functional characteristics of focal lesions such as cold (not trapping iodine) and warm (trapping iodine to the same extent as normal thyroid parenchyma) nodules. It is a basic radioisotope to detect metastatic lesions of differentiated tumours of the thyroid (following the surgical removal of the thyroid or radioisotopic ablation). Scintigraphy of thyroid gland and thyroid carcinoma metastases.
  - in the therapy of: nodular goitre, hyperthyroidism in Graves-Basedov’s disease, autonomic thyroid nodules, Plummer’s disease. This medicinal product is used for the thyroid residue ablation after surgery of differentiated thyroid cancers and in the treatment of differentiated thyroid carcinoma metastases.

- **Posology and method of administration:**
  Sodium iodide Na\(^{131}\)I, solution for injection is the formulation designed for the intravenous administration. The medicinal product can be administered directly to the patients in the various radioactivity doses, appropriate to the treatment and dependent on the purpose: the doses are different in the diagnostic and therapeutic procedures. The recommended therapeutic dose is dependent on clinical assessment performed by medical team. This dose should be established individually for each patient.

  *(for detailed information see SmPC)*

- **Calibration:**
  7 days

- **Radionuclidic purity:**
  ≥ 99.9%

- **Radiochemical purity:**
  ≥ 97%

- **Expiration:**
  28 days from the production date

- **Storage:**
  at temperature below 25ºC.

- **Package:**
  10 ml glass vials, closed with rubber stoppers and aluminum caps and placed inside a lead container.

Marketing authorization:
Poland, Colombia, Ukraine

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
Strontium chloride $^{89}$SrCl$_2$ POLATOM 37.5 MBq/ml
solution for injection
*Stronti ($^{89}$Sr) chloridi solutio injectabilis*

**Qualitative and quantitative composition:**
Strontium-89 chloride 37.5 MBq/ml. Strontium-89 is a pure beta emitter with an energy of 1.492 MeV and a half-life of 50.5 days.

**Excipients:**
Strontium chloride, sodium chloride, water for injection

**Indications:**
Strontium chloride $^{89}$SrCl$_2$ POLATOM is indicated:

► for the palliation of pain from bone metastases, the best documented use of strontium-89 chloride is in case of osteoblastic or mixed metastases from prostate cancer and breast cancer,

► in cases of other tumors resulting in osteoblastic (scintigraphically “hot”) metastases to the bone,

► most common indication for strontium chloride is the treatment of pain in patients with multiple disseminated metastases (chemotherapy, hormonal therapy, treatment with analgesics including narcotic drugs), who have not responded to previous conventional therapies. Bone scintigraphy is recommended prior to Strontium-89 chloride therapy.

**Posology and method of administration:**
Strontium chloride $^{89}$SrCl$_2$ POLATOM is administered as a single intravenous injection in a dose of 150 MBq activity in about 4 ml of the solution. Alternatively in particularly heavy or light framed patients a dose of 2 MBq/kg „fat-free” body weight may be used. This dosage is suitable for the elderly. Patient’s hospitalisation is not necessary. In case of recurrent pain a repeated administration of the radiopharmaceutical may be applied. Repeat administrations should not be performed within 3 months of the previous injection to reduce the risk of cumulative effects. Further administrations are not indicated in patients who have not responded to the previous administration. The product is not for administration to children.

(for detailed information see SmPC)

**Calibration:**
7 days

**Radionuclidic purity:**
$\geq 99.4\%$

**Expiry:**
28 days after reference date

**Storage:**
at temperature below 25ºC, do not freeze

**Package:**
10 ml glass vials, closed with rubber stoppers and aluminum caps and placed inside a lead container.

Marketing authorization:
Poland, Belarus, Ukraine

Contact:
Export Department +48 22 273 1820
email: export@polatom.pl
ItraPol
radiopharmaceutical precursor, solution
Yttrium ($^{90}$Y) chloride
code: PY-1

- **Qualitative and quantitative composition:**
  Each vial contains 0.925-37 GBq Yttrium ($^{90}$Y) on the reference date and time (corresponding to 46-1840 nanograms of Yttrium ($^{90}$Y) as Yttrium-90 chloride in a volume from 0.01 ml to 2 ml) in hydrochloric acid solution.

Yttrium ($^{90}$Y) is produced by decay of its radioactive precursor Strontium ($^{90}$Sr). It decays by emission of beta radiation with maximum energy 2.281 MeV (99.98%), to stable Zirconium ($^{90}$Zr).

Yttrium ($^{90}$Y) has a half-life of 2.67 days (64.1 hours).

- **Excipients:**
  Hydrochloric acid (concentrated), water for injections

- **Indications:**
  To be used only for the radiolabelling of medicinal products, which have been specifically developed and authorised for radiolabelling with this radionuclide.

Radiopharmaceutical precursor - not intended for direct use in patients.

- **Posology and method of administration:**
  The quantity of ItraPol required for radiolabelling and the quantity of Yttrium ($^{90}$Y)-labelled medicinal product that is subsequently administered will depend on the medicinal product radiolabelled and its intended use. Refer to the Summary of Product Characteristics/Package leaflet of the particular medicinal product to be radiolabelled.

ItraPol is intended for *in vitro* labelling of medicinal products which are subsequently administered by the approved route.

*(for detailed information see SmPC)*

- **Calibration:**
  3 days from the production date

- **Radionuclidic impurities:**
  $^{90}$Sr ≤ 0.002%
  other γ impurities ≤ 0.01%

- **Chemical impurities:**
  Cu, Zn, Co, Ni, Fe, Pb (single impurity ≤ 0.1 µg/GBq)

- **Expiration:**
  7 days from the date of manufacture

- **Storage:**
  In the original package, below 25°C

- **Package:**
  Colourless type 1 glass vial of 2 ml volume closed with a rubber stopper and aluminium seal, placed in a shielding lead container.

Pack size: 1 vial

During storage, due to ionising radiation, the vial may change color into yellow-brown.

This discoloration has no influence onto the product quality.

Marketing authorization in Poland
Contact:
Export Department +48 22 273 1820
e-mail: export@polatom.pl
LutaPol
radiopharmaceutical precursor, solution
Lutetium (\(^{177}\)Lu) chloride
code: PLu-1

- **Qualitative and quantitative composition:** Each vial contains 0.925-37 GBq Lutetium (\(^{177}\)Lu) on the reference date and time (corresponding to 1.86–74 micrograms of lutetium as lutetium-177 chloride in the volume from 0.01 ml to 2 ml) in hydrochloric acid solution.

- **Radionuclidic impurities:**
  \(^{177m}\)Lu ≤ 0.05%
  other γ impurities ≤ 0.01%

- **Chemical impurities:**
  Cu, Zn, Co, Ni, Fe, Pb (single impurity ≤ 0.1 µg/GBq)

- **Expiration:**
  7 days from the date of manufacture

- **Package:**
  In the original package, below 25ºC

- **Excipients:**
  Hydrochloric acid (concentrated), water for injections

- **Indications:**
  To be used only for the radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide.
  Radiopharmaceutical precursor - not intended for direct use in patients.

- **Chemical impurities:**
  Cu, Zn, Co, Ni, Fe, Pb (single impurity ≤ 0.1 µg/GBq)

- **Expiration:**
  7 days from the date of manufacture

- **Pack size:** 1 vial

  During storage, due to ionising radiation, the vial may change colour into yellow-brown. This discoloration has no influence onto the product quality.

- **Posology and method of administration:**
  The quantity of LutaPol required for radiolabelling and the quantity of Lutetium (\(^{177}\)Lu)-labelled medicinal product that is subsequently administered will depend on the medicinal product radiolabelled and its intended use.
  Refer to the Summary of Product Characteristics/Package leaflet of the particular medicinal product to be radiolabelled.

  LutaPol is intended for in vitro labelling of medicinal products which are subsequently administered by the approved route.

  *(for detailed information see SmPC)*

- **Calibration:**
  4 days from the production date

Marketing authorization in Poland

**Contact:**
Export Department +48 22 273 1820
email: export@polatom.pl
# Definitions, units, decay tables

**Radionuclidic purity:** the ratio, expressed as a percentage, of the radioactivity of the radionuclide concerned to the total radioactivity of the radiopharmaceutical preparation.

**Radiochemical purity:** the ratio, expressed as a percentage, of the radioactivity of the radionuclide concerned which is present in the radiopharmaceutical preparation in the stated chemical form, to the total radioactivity of that radionuclide present in the radiopharmaceutical preparation.

<table>
<thead>
<tr>
<th>99mTc decay</th>
<th>131I decay</th>
<th>Becquerel in Curie:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The half-live ($T_{1/2}$): 6.01 h</strong></td>
<td><strong>The half-live ($T_{1/2}$): 8.02 d</strong></td>
<td><strong>1 Bq = 27.027 pCi</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1 kBq = 27.027 nCi</strong></td>
</tr>
<tr>
<td><strong>HOURS</strong></td>
<td><strong>DAYS</strong></td>
<td><strong>1 MBq = 27.027 µCi</strong></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td><strong>1 GBq = 27.027 mCi</strong></td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td><strong>1 TBq = 27.027 Ci</strong></td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td><strong>Curie in Becquerel:</strong></td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td><strong>1 nCi = 37 Bq</strong></td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td><strong>1 µCi = 37 kBq</strong></td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td><strong>1 mCi = 37 MBq</strong></td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td><strong>1 Ci = 37 GBq</strong></td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td><strong>10 Ci = 0.37 TBq</strong></td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td><strong>Rad in Gray:</strong></td>
</tr>
<tr>
<td>9</td>
<td>14</td>
<td><strong>1 mRad = 10 µGy</strong></td>
</tr>
<tr>
<td>10</td>
<td>21</td>
<td><strong>1 Rad = 10 mGy</strong></td>
</tr>
<tr>
<td>11</td>
<td>30</td>
<td><strong>Gray in Rad:</strong></td>
</tr>
<tr>
<td>12</td>
<td>60</td>
<td><strong>1 mGy = 100 mRad</strong></td>
</tr>
<tr>
<td>24</td>
<td>80</td>
<td><strong>1 Gy = 100 Rad</strong></td>
</tr>
<tr>
<td>48</td>
<td>90</td>
<td><strong>Rem in Sievert:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1 mRem = 10 µSv</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1 Rem = 10 mSv</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Sievert in Rem:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>1 mSv = 100 mRem</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>15 v = 100 Rem</strong></td>
</tr>
</tbody>
</table>