POLATOM

Radiopharmaceuticals

National Centre for Nuclear Research
Radioisotope Centre POLATOM

www.polatom.pl

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Company profile

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}Tc-Tektrotyd radiopharmaceutical kit for diagnostic imaging of tumors expressing somatostatin receptors, useful in oncology, or ItraPol (^{90}Y solution for radiolabeling) and LutaPol (^{177}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.

When ordering, please specify the following information:

- **the product code**
- **name of the product**
- **activity**
- **quantity**
- **required shipping date**

Radionuclide generator $^{99}Mo/^{99m}Tc$

code: MTcG-4

Qualitative and quantitative composition:

Sodium pertechnetate (^{99m}Tc) injection is produced by means of a ($^{99}Mo/^{99m}Tc$) generator. Technetium (^{99m}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 x 10^5 years, can be regarded as quasi stable.

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

The ^{99}Mo on the column is in equilibrium with the formed daughter isotope ^{99m}Tc. The generators are supplied with the following ^{99}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}Mo is about 87%.

Examples of activities of radionuclide generators:

$^{99m}Tc/^{99}Mo$ activity [GBq] at production date	8.0 9.1	14 16	21 24	28 32	35 40	42 48	53 60.6	64 73.1	69 78.9	88 100.6	125 142.9	141 161.1	175 200
^{99m}Tc activity (maximal theoretical eluable activity at calibration date, 5 days after production, at 12am CET) [GBq]	2.3	4.0	6.0	8.0	10	12	15	18	20	25	35	40	50
^{99}Mo activity (at calibration date, 5 days after production, at 12am CET) [GBq]	2.6	4.5	6.8	9.2	11	14	17	21	22	29	41	46	57

The technetium (^{99m}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).

Eluate volume control from 4 ml to 8 ml allows to obtain the required radioactive concentration of pertechnetate-^{99m}Tc solution.

Expected radioactivity of eluted ^{99m}Tc on each exploitation day from the generators within standard range of nominal activities:

GBq	2.00	4.00	5.00	6.00	7.50	8.00	10.00	12.00	13.00	15.00	17.00	18.50	20.00	23.00	25.00	30.00	35.00	40.00	50.00	82.00
Day																				
-5	7.1	14.1	17.6	21.2	26.4	28.2	35.3	42.3	45.8	52.9	59.9	65.2	70.5	81.1	88.2	105.8	123.4	141.1	176.3	
-4	5.5	11.0	13.7	16.4	20.6	21.9	27.4	32.9	35.6	41.1	46.6	50.7	54.8	63.0	68.5	82.2	95.9	109.6	137.0	
-3	4.3	8.5	10.7	12.8	16.0	17.0	21.3	25.6	27.7	32.0	36.2	39.4	42.6	49.0	53.3	63.9	74.6	85.2	106.5	175.0
-2	3.3	6.6	8.3	9.9	12.4	13.2	16.6	19.9	21.5	24.8	28.1	30.6	33.1	38.1	41.4	49.7	57.9	66.2	82.8	136.0
-1	2.6	5.1	6.4	7.7	9.6	10.3	12.9	15.4	16.7	19.3	21.9	23.8	25.7	29.6	32.2	38.6	45.0	51.5	64.3	105.6
0	2.00	4.00	5.00	6.00	7.50	8.00	10.00	12.00	13.00	15.00	17.00	18.50	20.00	23.00	25.00	30.00	35.00	40.00	50.00	82.00
1	1.55	3.11	3.89	4.66	5.83	6.22	7.77	9.33	10.10	11.66	13.21	14.38	15.54	17.88	19.43	23.32	27.20	31.09	38.86	63.73
2	1.21	2.42	3.02	3.62	4.53	4.83	6.04	7.25	7.85	9.06	10.27	11.17	12.08	13.89	15.10	18.12	21.14	24.16	30.20	49.53
3	0.94	1.88	2.35	2.82	3.52	3.76	4.69	5.63	6.10	7.04	7.98	8.69	9.39	10.80	11.74	14.08	16.43	18.78	23.47	38.50
4	0.73	1.46	1.82	2.19	2.74	2.92	3.65	4.38	4.74	5.47	6.20	6.75	7.30	8.39	9.12	10.95	12.77	14.59	18.24	29.92
5	0.57	1.13	1.42	1.70	2.13	2.27	2.84	3.40	3.69	4.25	4.82	5.25	5.67	6.52	7.09	8.51	9.93	11.34	14.18	23.25
6	0.44	0.88	1.10	1.32	1.65	1.76	2.20	2.64	2.87	3.31	3.75	4.08	4.41	5.07	5.51	6.61	7.71	8.82	11.02	18.07
7	0.34	0.69	0.86	1.03	1.28	1.37	1.71	2.06	2.23	2.57	2.91	3.17	3.43	3.94	4.28	5.14	6.00	6.85	8.56	14.05
8	0,27	0.53	0.67	0.80	1.00	1.07	1.33	1.60	1.73	2.00	2.26	2.46	2.66	3.06	3.33	3.99	4.66	5.33	6.66	10.92
9	0.21	0.41	0.52	0.62	0.78	0.83	1.03	1.24	1.35	1.55	1.76	1.91	2.07	2.38	2.59	3.10	3.62	4.14	5.17	8.48
10	0.16	0.32	0.40	0.48	0.60	0.64	0.80	0.96	1.05	1.21	1.37	1.49	1.61	1.85	2.01	2.41	2.81	3.22	4.02	6.59
11	0.13	0.25	0.31	0.38	0.47	0.50	0.63	0.75	0.81	0.94	1.06	1.16	1.25	1.44	1.56	1.88	2.19	2.50	3.13	5.12
12	0.10	0.19	0.24	0.29	0.36	0.39	0.49	0.58	0.63	0.73	0.83	0.90	0.97	1.12	1.21	1.46	1.70	1.94	2.43	3.98
13	0.08	0.15	0.19	0.23	0.28	0.30	0.38	0.45	0.49	0.57	0.64	0.70	0.76	0.87	0.94	1.13	1.32	1.51	1.89	3.10
14	0.06	0.12	0.15	0.18	0.22	0.23	0.29	0.35	0.38	0.44	0.50	0.54	0.59	0.67	0.73	0.88	1.03	1.17	1.47	2.41
15	0.05	0.09	0.12	0.14	0.17	0.18	0.22	0.27	0.30	0.34	0.39	0.42	0.46	0.52	0.57	0.68	0.80	0.91	1.14	1.87

mCi	54.05	108.11	135.14	162.16	202.70	216.22	270.27	324.32	351.35	405.41	459.46	500.00	540.54	621.62	675.68	810.81	945.95	1081.08	1351.35	2216.21
Day																				
-5	190.62	381.08	475.68	572.97	713.51	762.16	954.05	1143.24	1237.84	1429.73	1618.92	1762.16	1905.40	2191.89	2383.78	2859.46	3335.13	3813.51	4764.86	
-4	148.13	297.30	370.27	443.24	556.76	591.89	740.54	889.19	962.16	1110.81	1259.46	1370.27	1481.08	1702.70	1851.35	2221.62	2591.89	2962.16	3702.70	
-3	115.14	229.73	289.19	345.95	432.43	459.46	575.68	691.89	748.65	864.86	978.38	1064.86	1151.35	1324.32	1440.54	1727.03	2016.21	2302.70	2878.38	4729.73
-2	89.46	178.38	224.32	267.57	335.13	356.76	448.65	537.84	581.08	670.27	759.46	827.03	894.59	1029.73	1118.92	1343.24	1564.86	1789.19	2237.84	3675.67
-1	69.54	137.84	172.97	208.11	259.46	278.38	348.65	416.22	451.35	521.62	591.89	643.24	694.59	800.00	870.27	1043.24	1216.22	1391.89	1737.84	2854.05
0	54.05	108.11	135.14	162.16	202.70	216.22	270.27	324.32	351.35	405.41	459.46	500.00	540.54	621.62	675.68	810.81	945.95	1081.08	1351.35	2216.21
1	42.00	84.05	105.14	125.95	157.57	168.11	210.00	252.16	272.97	315.13	357.03	388.65	420.00	483.24	525.13	630.27	735.13	840.27	1050.27	1722.43
2	32.65	65.41	81.62	97.84	122.43	130.54	163.24	195.95	212.16	244.86	277.57	301.89	326.49	375.41	408.11	489.73	571.35	652.97	816.22	1338.65
3	25.36	50.81	63.51	76.22	95.14	101.62	126.76	152.16	164.86	190.27	215.68	234.86	253.78	291.89	317.30	380.54	444.05	507.57	634.32	1040.54
4	19.73	39.46	49.19	59.19	74.05	78.92	98.65	118.38	128.11	147.84	167.57	182.43	197.30	226.76	246.49	295.95	345.13	394.32	492.97	808.65
5	15.32	30.54	38.38	45.95	57.57	61.35	76.76	91.89	99.73	114.86	130.27	141.89	153.24	176.22	191.62	230.00	268.38	306.49	383.24	628.38
6	11.92	23.78	29.73	35.68	44.59	47.57	59.46	71.35	77.57	89.46	101.35	110.27	119.19	137.03	148.92	178.65	208.38	238.38	297.84	488.38
7	9.27	18.65	23.24	27.84	34.59	37.03	46.22	55.68	60.27	69.46	78.65	85.68	92.70	106.49	115.68	138.92	162.16	185.13	231.35	379.73
8	7.19	14.32	18.11	21.62	27.03	28.92	35.95	43.24	46.76	54.05	61.08	66.49	71.89	82.70	90.00	107.84	125.95	144.05	180.00	295.13
9	5.59	11.08	14.05	16.76	21.08	22.43	27.84	33.51	36.49	41.89	47.57	51.62	55.95	64.32	70.00	83.78	97.84	111.89	139.73	229.19
10	4.35	8.65	10.81	12.97	16.22	17.30	21.62	25.95	28.38	32.70	37.03	40.27	43.51	50.00	54.32	65.14	75.95	87.03	108.65	178.11
11	3.38	6.76	8.38	10.27	12.70	13.51	17.03	20.27	21.89	25.41	28.65	31.35	33.78	38.92	42.16	50.81	59.19	67.57	84.59	138.38
12	2.62	5.14	6.49	7.84	9.73	10.54	13.24	15.68	17.03	19.73	22.43	24.32	26.22	30.27	32.70	39.46	45.95	52.43	65.68	107.57
13	2.05	4.05	5.14	6.22	7.57	8.11	10.27	12.16	13.24	15.41	17.30	18.92	20.54	23.51	25.41	30.54	35.68	40.81	51.08	83.78
14	1.59	3.24	4.05	4.86	5.95	6.22	7.84	9.46	10.27	11.89	13.51	14.59	15.95	18.11	19.73	23.78	27.84	31.62	39.73	65.14
15	1.26	2.43	3.24	3.78	4.59	4.86	5.95	7.30	8.11	9.19	10.54	11.35	12.43	14.05	15.41	18.38	21.62	24.59	30.81	50.54

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 ^{99}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 Authorizations:

Austria:	Poltechnet
Belarus:	Polgentec 2-120 GBq
Bulgaria:	Poltechnet
Columbia:	Polgentec 2-120 GBq
Czech Republic:	Poltechnet
Denmark:	Poltechnet
Georgia:	Polgentec 2-120 GBq
Greece:	Technegen 2-120 GBq
Germany:	Pertector
Lithuania:	Poltechgen 8,0-175 GBq, radionuklidų generatorius
Poland:	Poltechnet
Portugal:	Poltechnet
Romania:	Poltechnet 8.0-175 GBq generator de radionuclizi
Russia:	Polgentek
Slovenia:	Poltechnet 8-175 GBq, radionuklidni generator
Spain:	Poltechnet 8,0-175 GBq generador de radionúclido
Sweden:	Poltechnet
Switzerland:	Pertector Radionuklidgenerator
Ukraine:	Poltechnet
United Kingdom:	Pertector

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Accessories for radionuclide generator

Kit for Poltechnet elution code: MTcG-01

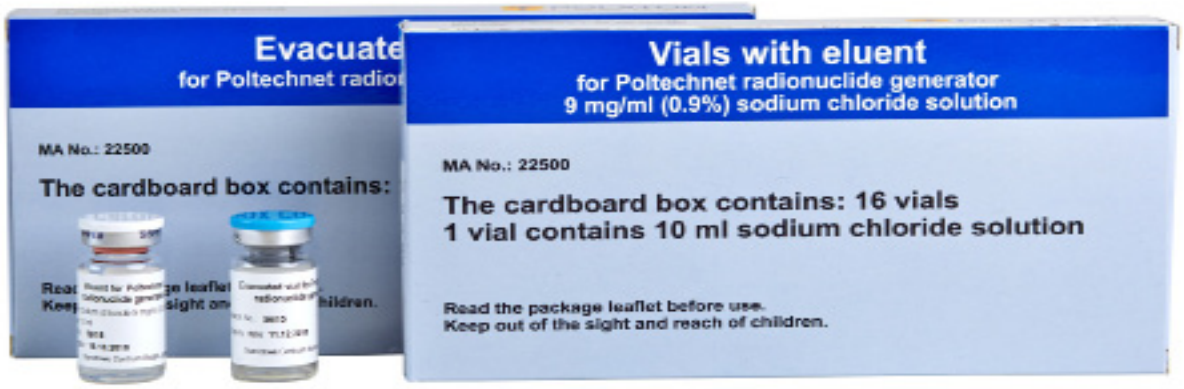
■ Content:

- 16 vials with eluent of 10 ml volume containing 9 mg/ml (0.9%) sodium chloride solution
- 16 evacuated vials of 10 ml volume

■ Expiration:
12 months

■ Storage:
< 25°C

Lead shield for eluate vial code: MTcG-02
Supplied f.o.c. with the first ordered generator



Kit for aluminium determination code: MTcA- 1

■ 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 cm^3 syringe — code: OS-2
- Lead shield for 5 cm^3 syringe — code: OS-5
- Lead shield for 5 cm^3 syringe — code: OS-5A
- Shielding stand for syringe — code: OS-P-10
- Tungsten shield for 2 cm^3 syringe — code: OSW-2
- Tungsten shield for 3 cm^3 syringe — code: OSW-3
- Tungsten shield for 5 cm^3 syringe — code: OSW-5
- Tungsten shield for 10 cm^3 syringe — code: OSW-10

lead shields for syringes

tungsten shields for syringes

Lead shield code	Length [mm]	Internal diameter [mm]
OS-2	51	10.5
OS-5	62	14.2
OS-5A	62	15.2
OS-P-10	160	19.0

Tungsten shield code	Length [mm]	Internal diameter [mm]
OSW-2	50	10.3 (11.0)*
OSW-3	52	11.0 (11.4)*
OSW-5	60	14.0 (15.0)*
OSW-10	71	18.0

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

Colloid,

Kit for radiopharmaceutical preparation

Stanni colloidalis et technetii (^{99m}Tc) solutio iniectabilis 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 ^{99m}Tc-Colloid, obtained by reconstitution of lyophilisate in 5 ml of sterile, bacterial endotoxins and oxidant free eluate from a radionuclide generator ^{99}Mo/^{99m}Tc with activity of 100-1000 MBq in accordance with the labelling instructions.

One vial of the product labelled with ^{99m}Tc 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 ^{99m}Tc-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: PoltechColloid
Belarus: ПолтехКоллоид
Georgia: PoltechColloid 0.17 mg

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

DMSA,

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) succimeri solutio iniectabilis 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 ^{99}Mo/^{99m}Tc, 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-^{99m}Tc (eluate from a radionuclide generator ^{99}Mo/^{99m}Tc) 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.

^{99m}Tc-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 25°C

■ Expiration:
the shelf life of the kit is 6 months 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: PoltechDMSA
Belarus: ПолтехДМСА
Colombia: Acido dimercaptosuccionicio (DMSA) polvo liofilizado para reconstituir a solucion inyectable (kit de preparacion del ^{99m}Tc-DMSA)
Georgia: PoltechDMSA 1 mg

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

DTPA

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) pentetatis solutio iniectabilis 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: PoltechDTPA
Australia: PENTASTAN Kit for preparation of Technetium(^{99m}Tc) pentetate powder for injection multidose vial
Belarus: Полтех ДТПА
Colombia: POLTECHDTPA
Georgia: PoltechDTPA 13.25 mg

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

MBrIDA

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) mebrofenini solutio iniectabilis 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 ^{99m}Tc-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 ^{99m}Tc-MBrIDA is administered intravenously after labelling with sterile, oxidant free eluate from radionuclide generator ^{99}Mo/^{99m}Tc in accordance with the labelling instructions.

Eluate of sodium pertechnetate-^{99m}Tc solution (eluate from radionuclide generator ^{99m}Mo/^{99m}Tc) 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: PoltechMBrIDA
Belarus: ПолтехМБрИДА
Colombia: Kit para la preparacion radiofarmaceutica 99mTc-MIBRIDA

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

MDP

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) medronati solutio iniectabilis code: MTcK-8

■ Qualitative and quantitative composition:
Methylenediphosphonic 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 methylenediphosphonic 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: PoltechMDP
Belarus: ПолтехМДП
Georgia: Kit for the preparation of radiopharmaceutical ^{99m}TC-MDP
Greece: BONESCAN

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

MIBI

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) sestamibi solutio iniectabilis 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-^{99m}Tc 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-^{99m}Tc 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:	ПолтехМИБИ
Colombia:	MIBI (Tetra (2-metoxi isobutil isonitrilo) Cobre I Tetrafluoroborato)
Finland:	SAMMIBI
France:	CARDIOMIBI 1mg, trousse pour préparation radiopharmaceutique
Georgia:	Kit for preparation of radiopharmaceutical ^{99m}Tc-MIBI
Germany:	CardioTOP
Greece:	Cardioscan
India:	PoltechMIBI
Italy:	MIBISPECT
Norway:	Sammibi
Poland	PoltechMIBI
Spain:	MIBI Institute of Atomic Energy 1 mg equipo de reactivos para preparacion radiopharmaceutica
Sweden:	Sammibi
Turkey:	Tc-99m MIBI
United Kingdom:	CARDIOVIS

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Pyrophosphate

Kit for radiopharmaceutical preparation

Stanni pyrophosphatis et technetii (^{99m}Tc) solutio iniectabilis 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:

- angiocardioscintigraphy 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 appropriate volume of solution prepared by dissolving contents of the vial in normal saline, and then administer intravenously sterile solution of sodium pertechnetate-^{99m}Tc (eluate from ^{99}Mo/^{99m}Tc generator).
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-^{99m}Tc and inject labelled erythrocytes into the patient.

In vivo/in vitro 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-^{99m}Tc. 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 reconstitution with normal saline, 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: PoltechRBC

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Tektrotyd

Kit for radiopharmaceutical preparation

HYNIC-[D-Phe^1,Tyr^3-Octreotide] trifluoroacetate code: MTcK-1

■ Qualitative and quantitative composition:
Vial I contains 20 micrograms of HYNIC-[D-Phe^1,Tyr^3-Octreotide] trifluoroacetate

■ Excipients:
Vial I: N-[tris(hydroxymethyl)methyl]glycine (Tricine), Stannous chloride dihydrate, Mannitol, Sodium hydroxide for pH adjustment, Hydrochloric acid for pH adjustment, Nitrogen (protective gas)
Vial II: Ethylenediamine-N,N'-diacetic acid (EDDA), Disodium phosphate dodecahydrate, Sodium hydroxide, Sodium hydroxide for pH adjustment, Hydrochloric acid for pH adjustment, Nitrogen (protective gas)

■ Indications:
This medicinal product is for diagnostic use only.
After radiolabelling with sodium pertechnetate (^{99m}Tc) solution, the solution of ^{99m}Tc-Tektrotyd obtained is indicated for use in adults as adjunct in the diagnosis and management of somatostatin receptor bearing neuroendocrine tumours (NET), by aiding their localization.
Tumours which do not bear somatostatin receptors will not be visualised.

■ Posology and method of administration:
► Posology
Adults - the suggested activity range is 370 to 740 MBq in one single intravenous injection. The activity to be administered depends on the available equipment.
Elderly population (above 65 years). No dose adjustment is required for elderly.
Renal impairment - careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.
Hepatic impairment - dosage reduction in hepatic impairment is not necessary.
Paediatric population - there are no data on safety and efficacy of ^{99m}Tc-Tektrotyd for the use in paediatric patients.
If alternative techniques not using ionising radiation are not available, 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.

► Method of administration
This medicinal product should be radiolabelled before administration to the patient.
^{99m}Tc-Tektrotyd is administered intravenously in a single dose.
For each patient, exposure to ionising radiation must be justifiable on the basis of likely diagnostic benefit and risk from radiation exposure.
For more convenient administration, the solution of ^{99m}Tc-Tektrotyd may be diluted with sodium chloride injection.
Image acquisition should be carried out at 1-2 and 4 hours after intravenous administration. Images at 1-2 hours post-injection may be useful for comparison and evaluation of abdominal activity imaged at 4 hours.
The examination may be complemented, depending on the clinical need, by acquisition 15 minutes and 24 hours post-injection of the tracer. It is recommended to carry out the examinations using whole body technique and SPECT (or SPECT/ CT) of selected body areas.
(for detailed information see SmPC)

■ Stability:
After reconstitution and radiolabelling 4 hours when stored below 25°C.

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

■ Storage:
Store in a refrigerator at 2°C - 8°C. During transportation (not longer than 5 days) up to 35°C.

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

Marketing authorization:
TEKTROTYD 20 μg in:
Bulgaria, Czech Republic, Denmark, Estonia, Finland, Hungary, Malta, Norway, Poland, Romania, Slovakia, Sweden
and TEKTROTYD 16 μg in:
Greece, Costa Rica, Columbia

TEKTROTYD 16 μg - distribution via ROTOP Pharmaka GmbH (MAH) in:
Austria, France, Germany, Great Britain, Italy, Portugal, Spain.

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Hippurate-^{131}I

solution for injection

Natrii iodohippurati (^{131}I) solutio iniectabilis 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:
≥ 99.9%

■ Radiochemical purity:
≥ 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: Hipuran-131I do wstrzykiwań
Belarus: ГИППУРАН-131I

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Meta-Iodobenzylguanidine^{131}I (MIBG-^{131}I)

for diagnostic use, solution for injection

Iobenguani (^{131}I) solutio iniectabilis ad usum diagnosticum code: MI-10D

■ Qualitative and quantitative composition:
Meta-Iodo[^{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:
Meta-Iodobenzylguanidine-^{131}I (MIBG-^{131}I) is a diagnostic radiopharmaceutical for gamma-scintigraphy.
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 neurondocrine 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-^{131}I image is superimposed on the image of kidneys, obtained after administering ^{99m}Tc-DTPA, or an image of the skeleton, obtained after administering ^{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.
(for detailed information see SmPC)

■ Calibration:
9 days from the production date

■ Radionuclidic purity:
≥ 99.9%

■ Radiochemical purity:
≥ 94%

■ Expiration:
9 days from the production date

■ Storage:
at temperature below [-15°C]. Protect from light. After defrosting 4 hours below 25°C. Transportation should be carried in dry ice.

■ Package:
MIBG-^{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:
Poland: Metajodobenzyloguanidyna-^{131}I (MIBG-^{131}I), do diagnostyki
Malta: Metaiodobenzylguanidine-^{131}I (MIBG-^{131}I) for diagnostic use

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Meta-Iodobenzylguanidine^{131}I (MIBG-^{131}I)

for therapeutic use, solution for injection

Iobenguani (^{131}I) solutio iniectabilis ad usum therapeuticum code: MI-10T

■ Qualitative and quantitative composition:
Meta-Iodo[^{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-^{131}I (MIBG-^{131}I) is a radiopharmaceutical used in cancer therapy. It is used in treating disseminated, malignant, metastatic lesions, such as pheochromocytoma, paraganglioma, neuroblastoma, neuroendocrine tumors of gestroenteropancreatic tract, and sometimes medullary thyroid carcinoma.

■ Posology and method of administration:
In cancer therapy using the MIBG-^{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-^{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

■ Radionuclidic purity:
≥ 99.9%

■ Radiochemical purity:
≥ 92%

■ Expiration:
4 days from the production date

■ Storage:
at temperature below [-15°C]. Protect from light. After defrosting 2 hours below 25°C. Transportation should be carried in dry ice.

■ Package:
MIBG-^{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:
Poland: Metajodobenzyloguanidyna-^{131}I (MIBG-^{131}I), do terapii

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Meta-Iodobenzylguanidine^{123}I (MIBG-^{123}I)

solution for injection

Iobenguani (^{123}I) solutio iniectabilis code: MI-23

■ Qualitative and quantitative composition:
Meta-iodo[^{123}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}I (MIBG-^{123}I) is a radiopharmaceutical product used in scintigraphic detection and treatment monitoring of primary or metastatic pheochromocytoma or neuroblastoma.
The use of MIBG-^{123}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}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}I administration.
(for detailed information see SmPC)

■ Calibration:
at 10 am on next day after production

■ Radionuclidic purity:
> 99.65%

■ Radiochemical purity:
≥ 95%

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

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

■ Package:
MIBG-^{123}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:
Poland: Metajodobenzyloguanidyna-^{123}I (MIBG-^{123}I), do wstrzykiwań

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

$Na_2H^{32}PO_4$ sodium orthophosphate
solution for injection

Natrii phosphatis (^{32}P) solutio iniectabilis code: MP-9

■ Qualitative and quantitative composition:
$Na_2H^{32}PO_4$ sodium orthophosphate, 37-370 MBq/ml

■ Excipients:
Disodium hydrogenphosphate dodecahydrate, sodium chloride, water for injection

■ Indications:
$Na_2H^{32}PO_4$ 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.

^{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:
$Na_2H^{32}PO_4$ 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 ^{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

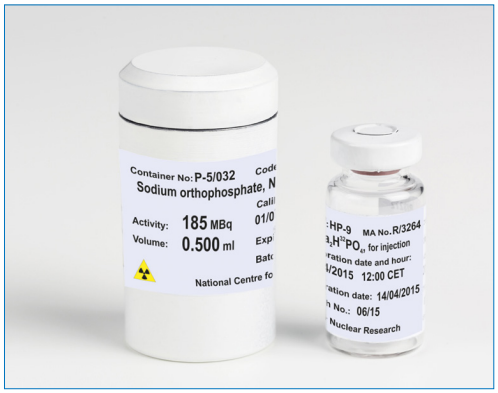
■ Radionuclidic purity:
≥ 97%

■ Radiochemical purity:
≥ 95%

■ Expiration:
21 days from the production date

■ Storage:
at temperature below 25°C

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



Marketing authorization:
Poland: Ortofosforan sodu, $Na_2H^{32}PO_4$ roztwór do wstrzykiwań
Belarus: ОРТОФОСФАТ НАТРИЯ $Na_2H^{32}PO_4$

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Sodium iodide $Na^{131}I$

capsules for diagnostic use. Hard capsules, 1–37 MBq

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

■ Qualitative and quantitative composition:
Sodium iodide ($Na^{131}I$) [1-37 MBq]

■ Excipients:
Sodium carbonate, sodium hydrogen carbonate, 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 $Na^{131}I$ POLATOM, capsules for diagnostic use, is a preparation for oral administration. In diagnostics, the oral administration of 1-4 MBq of sodium iodide ($Na^{131}I$) 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.
(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 25ºC

■ Package:
Sodium iodide $Na^{131}I$ POLATOM, capsules for diagnostic use, are supplied in two types of immediate packages.
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.
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.

Marketing authorization:
Poland: Jodek sodu $Na^{131}I$ POLATOM kapsułki do diagnostyki
Belarus: НАТРИЯ ИОДИД $Na^{131}I$ ПОЛАТОМ капсулы для диагностики
Colombia: Yoduro sodico-131 capsulas
Georgia: Sodium iodide Na131I POLATOM, capsules for therapeutic use

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Sodium iodide $Na^{131}I$

capsules for therapeutic use. Hard capsules, 37–5500 MBq

Natrii iodidi (^{131}I) capsulae ad usum therapeuticum code: MI-4T

■ Qualitative and quantitative composition:

Single hard capsule contains sodium iodide (^{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 hydrogenphosphate dihydrate, 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 $Na^{131}I$ 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:	Jodek sodu $Na^{131}I$ POLATOM kapsułki do terapii
Belarus:	НАТРИЯ ИОДИД $Na^{131}I$ ПОЛАТОМ капсулы для терапии
Colombia:	Yoduro sodico-131 capsulas
Costa Rica:	Yoduro de sodio Na ^{131}I POLATOM capsulas
South Korea:	Thyrokey P therapeutic sodium iodide I-131 capsule
Ukraine:	НАТРІЮ ЙОДИД $Na^{131}I$ ПОЛАТОМ

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Sodium iodide $Na^{131}I$

solution for injection

Natrii Iodidi (^{131}I) solutio

code: MI-2

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

■ Excipients:
Sodium carbonate, sodium hydrogen carbonate, 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 25°C.

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

Marketing authorization:
Poland: Jodek sodu $Na^{131}I$ roztwór do wstrzykiwań
Colombia: Sodium iodide, $Na^{131}I$, injection solution yoduro de sodio, $Na^{131}I$, solucion inyectable
Russia: Натрия иодид $Na^{131}I$
Ukraine: НАТРІЮ ЙОДИД $Na^{131}I$ ДЛЯ ІН'ЄКЦІЙ

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Strontium chloride $^{89}SrCl_2$
solution for injection
Stronti (^{89}Sr) chloridi solutio iniectabilis code: MSr-1

■ 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 (scintigraphicaly "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 inravenous 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:
≥ 99.4%

■ Expiration:
28 days after reference date

■ Storage:
at temperature below 25°C, do not freeze

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

Marketing authorization:
Poland: Chlorek strontu $^{89}SrCl_2$ POLATOM
Belarus: СТРОНЦИЯ ХЛОРИД $^{89}SrCl_2$ ПОЛАТОМ
Ukraine: СТРОНЦІЮ ХЛОРИД $^{89}SrCl_2$ ПОЛАТОМ

Contact:
Export Department +48 22 273 1820
email: polatom@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 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:

$^{90}Sr \leq 0.002\%$

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 I 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:
Poland: ItraPol

Contact:
Export Department +48 22 273 1820
email: polatom@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.
Lutetium (^{177}Lu) decays to stable Hafnium (^{177}Hf). It decays by emission of β^- particles with maximum energy 498 keV (average 149.2 keV) and emission of gamma radiation with prominent energies 208 keV (10.4%) and 113 keV (6.2%). Lutetium (^{177}Lu) has a half-life of 6.65 days.
Lutetium (^{177}Lu) is produced in nuclear reactor by neutron irradiation of Lutetium enriched in isotope (^{176}Lu). Such obtained Lutetium (^{177}Lu) contains stable Lutetium (^{176}Lu) as carrier. The specific activity of Lutetium (^{177}Lu) in pharmaceutical product LutaPol is higher than 500 GBq/mg of Lutetium on the calibration day.

■ 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.

■ 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

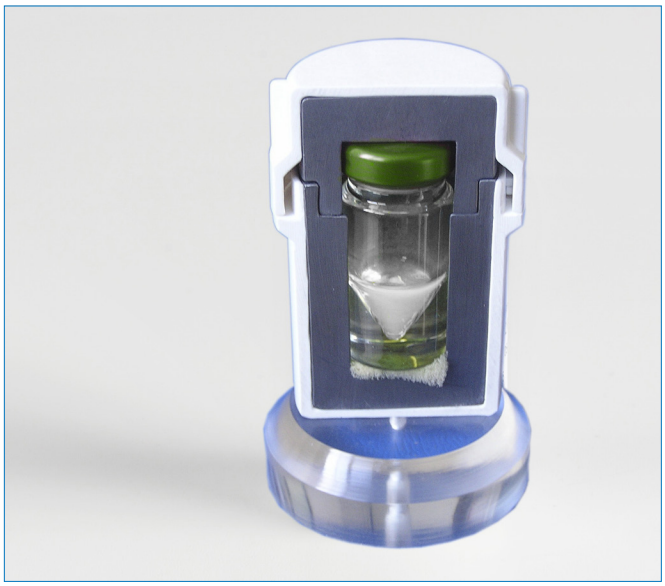
■ Radionuclidic impurities:
^{177m}Lu ≤ 0.05%
other γ impurities ≤ 0.01%

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

■ Expiration:
7 days from the date of manufacture

■ Storage:
In the original package, below 25°C

■ Package:
Colourless type I glass vial of 2 ml sealed with rubber stopper and an aluminium crimp cap, placed in lead shielding container.
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.



Marketing authorization:
Poland: LutaPol
Colombia: LUTAPOL

Contact:
Export Department +48 22 273 1820
email: polatom@polatom.pl

Products for research purposes
GMP grade

■ DOTATATE kits for ^{90}Y or ^{177}Lu radiolabelling
- DOTATATE AA 0.1 mg kit for direct radiolabelling (with ascorbic acid)
- DOTATATE AA 0.25 mg kit for direct radiolabelling (with ascorbic acid)

■ PEPTIDES
- DOTATATE 0.25 mg peptide
- DOTATATE 0.1 mg peptide
- DOTATATE 1.0 mg peptide

■ Kits for ^{68}Ga radiolabelling
- DOTATATE 40 μg (with sodium acetate: 70 mg/vial)
  kit for direct ^{68}Ga radiolabelling with max. 5mL of $^{68}GaCl_3$ in 0.1M HCl
- DOTATATE 40 μg (with sodium acetate: 35 mg/vial)
  kit for direct ^{68}Ga radiolabelling with max. 4mL of $^{68}GaCl_3$ in 0.05M HCl
- PSMA kit for ^{68}Ga radiolabelling with $^{68}GaCl_3$ in 0.05 or 0.1M HCl

■ EXCIPIENTS
- Ascorbic acid 50 mg (buffer solution for ^{90}Y or ^{177}Lu labelling)
- Ascorbic acid 100 mg (buffer solution for ^{90}Y or ^{177}Lu labelling)
- Sodium acetate 100 mg (buffer solution for ^{68}Ga labelling)

Contact:
Export Department +48 22 273 1820
email: polatom@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.

^{99m}Tc decay

The half-live ($T_{1/2}$): 6.01 h

HOURS	Activity
0	1.000
1	0.891
2	0.794
3	0.708
4	0.631
5	0.562
6	0.501
7	0.447
8	0.398
9	0.355
10	0.316
11	0.282
12	0.251
24	0.063
48	0.004

^{131}I decay

The half-live ($T_{1/2}$): 8.02 d

DAYS	Activity
0	1.000
1	0.917
2	0.841
3	0.772
4	0.708
5	0.649
6	0.595
7	0.546
8	0.501
14	0.298
21	0.163
30	0.075
60	0.006
80	0.001
90	0.000

Becquerel in Curie:

1Bq = 27.027 pCi
1kBq = 27.027 nCi
1MBq = 27.027 μCi
1GBq = 27.027 mCi
1TBq = 27.027 Ci

Curie in Becquerel:

1nCi = 37 Bq
1μCi = 37 kBq
1mCi = 37 MBq
1Ci = 37 GBq
10Ci = 0.37 TBq

Rad in Gray:

1mRad = 10 μGy
1Rad = 10 mGy

Gray in Rad:

1mGy = 100 mRad
1Gy = 100 Rad

Rem in Sievert:

1mRem = 10 μSv
1Rem = 10 mSv

Sievert in Rem:

1mSv = 100 mRem
1Sv = 100 Rem

2017

POLATOM

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