



POLATOM

Radiopharmaceuticals



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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 $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$

Poltechnet

code: MTcG-4

■ Qualitative and quantitative composition:

Sodium pertechnetate ($^{99\text{m}}\text{Tc}$) injection is produced by means of a ($^{99}\text{Mo}/^{99\text{m}}\text{Tc}$) generator. Technetium ($^{99\text{m}}\text{Tc}$) 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 2.13×10^5 years, can be regarded as quasi stable.

The radionuclide generator containing the parent isotope ^{99}Mo , adsorbed on a chromatographic

column delivers sodium pertechnetate- $^{99\text{m}}\text{Tc}$ injection in sterile solution.

The ^{99}Mo on the column is in equilibrium with the formed daughter isotope $^{99\text{m}}\text{Tc}$. 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:

$^{99\text{m}}\text{Tc}/^{99}\text{Mo}$ 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
$^{99\text{m}}\text{Tc}$ 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 ($^{99\text{m}}\text{Tc}$) 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).



Eluate volume control from 4 ml to 8 ml allows to obtain the required radioactive concentration of pertechnetate- $^{99\text{m}}\text{Tc}$ 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	277.03	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	61.68	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 $\mu\text{g/ml}$
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.

WARNING: For elution of the generator, use only vials with eluent manufactured by the same manufacturer.

WARNING: Do not rinse needles and stoppers with ethyl alcohol, ethyl ether or any detergent solution as this may interfere with the elution process

Marketing Authorizations:

Austria:	Poltechnet
Belarus:	Polgentec 2-120 GBq
Bulgaria:	Полтехнет
Columbia:	Polgentec 2-120 GBq
Czech Republic:	POLTECHNET
Denmark:	Poltechnet
Georgia:	Polgentec 2-120 GBq
Germany:	Pertector
Great Britain:	Pertector
Greece:	Technegen
Lithuania:	Poltechgen 8,0-175 GBq, radionuklidų generatorius
Malta:	Poltechnet
Marocco:	Poltechnet
Poland:	Poltechnet
Portugal:	Poltechnet
Romania:	Poltechnet 8.0-175 GBq generator de radionuclizi
Russia:	Полгентек
Slovenia:	Poltechnet 8-175 GBq, radionuklidni generator
South Korea:	Poltechnet
Sweden:	Poltechnet
Taiwan:	Poltechnet
Ukraine:	Poltechnet

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

Syringe shieldings

- ▶ Lead shield for 2 cm³ syringe
- ▶ Lead shield for 5 cm³ syringe
- ▶ Lead shield for 5 cm³ syringe
- ▶ Shielding stand for syringe
- ▶ Tungsten shield for 2 cm³ syringe
- ▶ Tungsten shield for 3 cm³ syringe
- ▶ Tungsten shield for 5 cm³ syringe
- ▶ Tungsten shield for 10 cm³ syringe

code: OS-2

code: OS-5

code: OS-5A

code: OS-P-10

code: OSW-2

code: OSW-3

code: OSW-5

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

PoltechColloid

Kit for radiopharmaceutical preparation

Stanni colloidalis et technetii (^{99m}Tc) solutio iniectabilis ode: 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 $^{99}\text{Mo}/^{99m}\text{Tc}$ with activity of 100-1000 MBq in accordance with the labelling instruction.

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.

Adults

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.

Pediatric population

The use of the product in pediatric 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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box



Marketing authorization:

Poland: PoltechColloid

Belarus: ПолтехКоллоид

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

DMSA

Kit for radiopharmaceutical preparation

Techne^{99m}Tc succimeri solutio iniectionabilis

PoltechDMSA

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:

The radiopharmaceutical ^{99m}Tc-DMSA is administered intravenously after labelling with sterile, oxidant-free eluate of sodium pertechnetate (^{99m}Tc) solution from a radionuclide generator ⁹⁹Mo/^{99m}Tc, in accordance with the labelling instruction.

For radiolabelling of one kit vial the 5 ml of sodium pertechnetate (^{99m}Tc) solution with activity of 100 - 7400 MBq should be used. This amount is sufficient to perform the examination in several adult patients. The image acquisitions may be performed two to three hours post-injection. If significant hydronephrosis exists late images or furosemide injection may then be useful (4 to 24 hours).

Adults

The activity recommended for a single examination in adult patient ranges from 75 to 150 MBq. However depending on indications a higher administered activity may be justifiable.

Pediatric population

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.

The activity for children is adjusted according to body weight or surface area.

(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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box



Marketing authorization:

Poland: PoltechDMSA

Belarus: ПолтехДМСА

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

DTPA

PoltechDTPA

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) pentetatis solutio iniectionabilis

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)
- ▶ GFR measurement from the plasma samples
- ▶ 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 $^{99}\text{Mo}/^{99m}\text{Tc}$, in accordance with the labelling instructions.

For radiolabelling of one vial the 5 ml of sodium pertechnetate (^{99m}Tc) solution (eluate from a radionuclide generator $^{99}\text{Mo}/^{99m}\text{Tc}$) with activity of 740-1500 MBq should be used.

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

Renal scintigraphy with measurement of glomerular filtration rate: Sequential scanning should begin immediately after injection. Optimal static imaging time is 1 hour post injection.

Brain scanning: Sequential dynamic scanning should begin immediately after injection. Static images are obtained 1 hour and, if necessary, several hours after injection.

Adults

The activity recommended for a renal scintigraphy in adult patient ranges from 74-370 MBq, for measurement of glomerular filtration rate from plasma it ranges 1.8-3.7 MBq, for angiography and brain scanning ranges 370-555 MBq, however depending on indications other activities may be justifiable.

Pediatric population

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.

The activity for children is adjusted according to body weight or surface area.

(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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box



Marketing authorization:

Poland: PoltechDTPA

Australia: PENTASTAN, kit for preparation of Technetium(^{99m}Tc) pentetate injection

Belarus: Полтех ДТПА

Colombia: POLTECHDTPA

Cyprus: POLTECHDTPA

Ukraine: Полтех ДТПА

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

MBrIDA

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) mebrofenini solutio injectabilis

PoltechMBrIDA

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 intended for:

- hepatobiliary imaging
- hepatobiliary function studies.

■ Posology and method of administration:

The radiopharmaceutical ^{99m}Tc -MBrIDA is administered intravenously after labelling with sterile, oxidant-free eluate of sodium pertechnetate (^{99m}Tc) solution from a radionuclide generator $^{99}\text{Mo}/^{99m}\text{Tc}$, in accordance with the labelling instruction.

For radiolabelling of one kit vial the sodium pertechnetate (^{99m}Tc) solution with activity of 370 - 1500 MBq should be used. This amount is sufficient to perform the examination in several (1-10) adult patients.

Adults

The activity recommended for a single examination in adult patient ranges from 111 to 185 MBq. Higher administered activity may be justifiable in hyperbilirubinaemia.

Pediatric population

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. The activity for children is adjusted according to body weight or surface area
(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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box



Marketing authorization:

Poland: PoltechMBrIDA
Belarus: ПолтехМБРИДА
Colombia: POLTECHMIBRIDA

Contact:

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

MDP

PoltechMDP

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) medronati solutio iniectionabilis

code: MTcK-8

■ Qualitative and quantitative composition:

methylenediphosphonic acid 5 mg
as sodium methylenediphosphonate 6.25 mg.

■ Excipients:

Stannous chloride dihydrate, 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.

■ Posology and method of administration:

The radiopharmaceutical ^{99m}Tc -MDP is administered intravenously after labelling with sterile, oxidant-free eluate from a radionuclide generator $^{99}\text{Mo}/^{99m}\text{Tc}$, in accordance with the labelling instruction.

For radiolabelling of one vial the 5 ml of sodium pertechnetate (^{99m}Tc) solution with activity of 1100-18500 MBq should be used.

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.

Adults

The activity recommended for a single examination of skeletal system in adult patient ranges from 370 to 740 MBq, however depending on indications other activities may be justifiable.

Pediatric population

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)

■ 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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box



Marketing authorization:

Poland: PoltechMDP

Australia: MDP Kit for preparation
of Technetium (^{99m}Tc) medronate
powder for injection vial

Belarus: ПолтехМДП

Cyprus: BONESCAN

Georgia: Kit for the preparation
of radiopharmaceutical ^{99m}Tc -MDP

Greece: BONESCAN

Ukraine: Полтех МДП

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Kit for radiopharmaceutical preparation

Technetii (^{99m}Tc) sestamibi solutio iniectionis

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.

Adults

The suggested dose range for intravenous administration to a patient of average is calculated per weight of 70 kg, depending on diagnosis purpose.

Pediatric population

The use of PoltechMIBI in pediatric 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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box

Marketing authorization:

Poland:	PoltechMIBI
Austria:	CardioTOP
Belarus:	ПолтехМИБИ
Colombia:	POLTECHMIBI
Cyprus:	CARDIOSCAN
Finland:	SAMMIBI
France:	CARDIOMIBI 1mg, trousse pour préparation radiopharmaceutique
Georgia:	Kit for preparation of radiopharmaceutical ^{99m} Tc-MIBI
Germany:	CardioTOP
Great Britain:	CARDIOVIS
Greece:	Cardioscan
India:	PoltechMIBI
Italy:	MIBISPECT
Norway:	Sammibi
Romania:	FID-MIBI 1 mg kit pentru preparat radiofarmaceutic
Spain:	MIBI Institute of Atomic Energy 1 mg equipo de reactivos para preparacion radiopharmaceutica
Sweden:	Sammibi
Turkey:	Tc-99m MIBI
Ukraine:	Полтех МІБІ

Contact:

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

Pyrophosphate

PoltechRBC

Kit for radiopharmaceutical preparation

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

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 $^{99}\text{Mo}/^{99m}\text{Tc}$ 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. During transportation (not longer than 7 days) up to 35°C.

■ Package:

3 or 6 vials in the cardboard box

Marketing authorization:

Poland: PoltechRBC

Cyprus: POLTECHRBC, powder for injectia

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Tektrotyd

Kit for radiopharmaceutical preparation

HYNIC-[D-Phe¹, Tyr³-Octreotide] trifluoroacetate

code: MTcK-1

■ Qualitative and quantitative composition:

Vial I contains 20 micrograms of HYNIC-[D-Phe¹, Tyr³-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.

Tumors which do not bear somatostatin receptors will not be visualized.

■ Posology and 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.

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.

Pediatric population

There are no data on safety and efficacy of ^{99m}Tc-Tektrotyd for the use in pediatric 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. Because of the potential hazard of ionising radiation, ^{99m}Tc-Tektrotyd should not be used in children under 18 years of age, unless the value of the expected clinical information is considered to outweigh the possible risk from radiation.

(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:

Poland, Belarus, Bulgaria, Czech Republic, Denmark, Estonia, Finland, Hungary, Malta, Norway, Romania, Russia, Slovakia, Sweden, Ukraine

and TEKTROTYD 16 µg in:

Poland, Austria, Columbia, Costa Rica, Cyprus, France, Germany, Great Britain, Greece, Italy, Portugal, Spain, Switzerland

TEKTROTYD 16 µg - distribution via ROTOP Pharmaka GmbH (MAH) in:

Austria, France, Germany, Great Britain, Italy, Spain.

Contact:

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

Hippurate-¹³¹I

solution for injection

Natrii iodohippurati (¹³¹I) solutio iniectionabilis

code: MI-18

■ Qualitative and quantitative composition:

Sodium 2-[¹³¹I]iodohippurate 3.7-74 MBq/ml

■ Excipients:

Benzyl alcohol, sodium chloride, water for injection

■ Indications:

Hippurate-¹³¹I 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
- 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-¹³¹I 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-¹³¹I 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. During transportation, not longer than 7 days after production date, up to 25 °C

■ Package:

10 ml glass vial sealed with a rubber stopper and an aluminum crimp cap, placed in a lead shielding container. The vial contains a volume of the solution corresponding to the activity determined on the calibration day.



Marketing authorization:

Poland: Hipuran-131I do wstrzykiwań

Belarus: ГИППУРАН-131I

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Meta-Iodobenzylguanidine¹³¹I (MIBG-¹³¹I)

for diagnostic use, solution for injection

iobenguani (¹³¹I) solutio iniectionis ad usum diagnosticum code: MI-10D

■ Qualitative and quantitative composition:

iobenguane (¹³¹I) 10 – 37 MBq/ml

■ Excipients:

bis[(3-iodobenzyl)guanidine]sulphate, sodium metabisulphite, copper (II) sulphate pentahydrate, sodium acetate trihydrate, acetic acid, benzyl alcohol, sodium chloride, water for injection

■ Indications:

- ▶ Isotope diagnostics (detection, localization, staging, treatment monitoring) of neuroendocrine tumors. These are in particular: pheochromocytoma, neuroblastoma, carcinoid tumors, medullary thyroid carcinoma.
- ▶ Evaluation of iobenguane (¹³¹I) uptake and retention to determine a diagnostic dose of iobenguane (¹³¹I).
- ▶ Treatment monitoring by assessing the uptake and spread of pathological foci taking up iobenguane (¹³¹I).
- ▶ Confirmation of neuroendocrine character of tumors with unknown origin.

■ Posology and method of administration:

Adults

The dose administered to adults is:

40-80 MBq (1.2 – 2.2 mCi).

No special dosage-scheme is required for the elderly patient.

Pediatric population

The dose administered to children can be calculated by modifying adults dose considering the weight or body surface of child.

In order to obtain images of sufficient quality the recommended minimum dose for children is 35 MBq.

The dose is administered intravenously; the duration of the injection should be 30-300 seconds.

Prior to administration, ensure emergency cardiac antihypertensive treatments are readily available.

When diagnostic administration for pheochromocytoma is planned attention is to be given to the interference with uptake of iobenguane (¹³¹I) by medication for control of hypertension. Incompatible medication should be stopped at least 2 weeks prior to the planned diagnostic administration. If necessary propranolol can be used instead.

Patients are to be well hydrated.

Thyroid blockade using stable iodine should be started 1 day before the iobenguane (¹³¹I) is

administered and continued for at least 2-3 days (according to ENAM 2008). Blockade by potassium iodide, potassium-iodate or Lugol's solution must be performed with an equivalent of 100 mg of iodine/day. Blockade by potassium perchlorate is achieved by administration of approximately 400 mg/day. It is recommended for children to administer potassium iodide (started 1 day before examination and finishing 1 day after).

(for detailed information see SmPC)

■ Calibration:

7 days from the production date

■ Radionuclidic purity:

≥ 99.9%

■ Radiochemical purity:

≥ 94%

■ Expiration:

7 days from the manufacturing date (expiry date is stated on the label)

■ Storage:

at temperature below [-15°C]. Protect from light. After defrosting store below 25°C, up to 4 hours. Transportation should be carried in dry ice.

■ Package:

MIBG-¹³¹I 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: Metajodobenzylguanidyna-¹³¹I (MIBG-¹³¹I), do diagnostyki

Malta: Metaiodobenzylguanidine-¹³¹I (MIBG-¹³¹I) for diagnostic use

Contact:

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

Meta-Iodobenzylguanidine¹³¹I (MIBG-¹³¹I)

for therapeutic use, solution for injection

iobenguani (¹³¹I) solutio iniectabilis ad usum therapeuticum code: MI-10T

■ Qualitative and quantitative composition:

iobenguane (¹³¹I): 370 - 740 MBq/ml

■ Excipients:

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

■ Indications:

Radiation therapy of tumors-tissue that is capable of retaining iobenguane. These are tumors arising from cells originating embryologically from the neural crest: pheochromocytomas, neuroblastomas, carcinoids and medullary carcinomas of the thyroid gland (MCT).

■ Posology and method of administration:

There is two-way selection of therapeutic activity of iobenguane (¹³¹I). Iobenguane (¹³¹I) can be administered:

- Therapeutic dose with an amount of iobenguane (¹³¹I) individually tailored on the basis of a dosimetric study. The dose as well as the interval(s) between possible multiple administrations are mainly determined by haematological radio-toxicity and the kind of tumour. The more rapid the rate of progression of the tumour, the shorter the interval.
- The "fixed" therapeutic dose (usually 3.7 – 11.1 GBq).

These recommended dosages are identical for children (must not be given to premature babies or neonates) and adults. No special dosage scheme is required for the elderly patient.

The therapeutic dose is administered intravenously, generally as an infusion over a period 1.5 – 4 hours. About 1 hour prior to administration the vial of iobenguane (¹³¹I) contained within its lead shield should be thawed by placing it in a water bath at temperature not exceeding 50°C. It is recommended that after thawing, immediately prior to administration by intravenous infusion, the dose be diluted with 50 ml sterile physiological saline for infusion.

(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 manufacturing date (expiry date is stated on the label).

■ Storage:

at temperature below [-15°C]. Protect from light. After defrosting store below 25°C for up to 2 hours. Transportation should be carried in dry ice.

■ Package:

MIBG-¹³¹I 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: Metajodobenzylguanidyna-¹³¹I
(MIBG-¹³¹I), do terapii

Contact:

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

Meta-Iodobenzylguanidine¹²³I (MIBG-¹²³I)

solution for injection

lobenguani (¹²³I) *solutio iniectabilis*

code: MI-23

■ Qualitative and quantitative composition:

lobenguane (¹²³I): 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:

► Diagnostic scintigraphic localisation of tumours originating in tissue that embryologically stems from the neural crest. These are pheochromocytomas, paragangliomas, chemodectomas and ganglioneuromas.

- Detection, staging and follow-up on therapy of neuroblastomas.

- Evaluation of the uptake of lobenguane. The sensitivity to diagnostic visualisation is different for the listed pathologic entities. Pheochromocytomas and neuroblastomas are sensitive in approx. 90 % of patients, carcinoids in 70 % and MCT in only 35 %.

► Functional studies of the adrenal medulla (hyperplasia) and the myocardium (sympathetic innervation).

■ Posology and method of administration:

lobenguane (¹²³I) is administered by slow i.e. injection or infusion. If desired the administration volume can be increased by dilution.

Pediatric population

In children the dosage should be chosen, dependent on body weight.

lobenguane (¹²³I) is administered according to the following dosage scheme:

- Children under 6 months: 4 MBq per kg body weight (max. 40 MBq).
- Children between 6 months and 2 years: 4 MBq per kg body weight (min. 40 MBq).
- Children over 2 years: a fraction of the adult dosage should be chosen, dependent on body weight

Adults

The recommended dosage is 80-200 MBq.

In the case of the sympathetic innervation of the myocardium studies the suggested dosage is 111 - 370 MBq for adults and not less than 80 MBq for children.

The above recommended dosage scheme should also consider the principles set out by local regulations for dose radiopharmaceuticals.

No special dosage-scheme is required for the elderly patient.

(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-¹²³I should be stored at temperature below 25°C. Protect from light.

■ Package:

MIBG-¹²³I 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: Metajodobenzylguanidyna-¹²³I

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Sodium iodide Na¹³¹I

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

Natrii iodidi (¹³¹I) capsulae ad usum diagnosticum

code: MI- 4D

■ Qualitative and quantitative composition:

Single hard capsule contains sodium iodide [¹³¹I] *Natrii iodidi* (¹³¹I) in the radioactivity range [1-37 MBq]

■ Excipients:

Sodium carbonate, sodium hydrogen carbonate, disodium hydrogen phosphate dihydrate, sodium thiosulphate pentahydrate, hard gelatin capsule.

■ Indications:

This product is used for diagnosis:

- ▶ 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.
- ▶ to study radioiodine location in thyroid tissue. An estimation of the thyroid uptake and its effective half-life can be used to calculate the dose absorbed from the activity of radioiodine planned for therapy.
- ▶ in the management of patients with differentiated thyroid carcinoma to identify the remaining thyroid tissue and in the metastases diagnostics.

■ Posology and method of administration:

Sodium iodide Na¹³¹I POLATOM, capsules for diagnostic use is a medicinal product for oral administration.

Adults

The recommended activities for an adult patient (70 kg) are as follows:

- for the scintigraphic thyroid diagnosis and thyroid uptake studies: 0.15-4 MBq of sodium iodide (¹³¹I) 24 hours prior the examination. Depending on the indication, the thyroid uptake study is conducted also 4-6 hours after capsule administration and then again in the first few days.
- for diagnosis in patients treated for thyroid differentiated carcinoma (for metastases and thyroid remnant identification): 37-240 MBq (usually 37-74 MBq) of sodium iodide [¹³¹I]. The whole body scintigraphy is usually conducted 72 hours (or more) after sodium iodide [¹³¹I] administration.

Pediatric population

The use of radioiodine in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. There should be borne in mind that the

late undesirable effects connected with sodium iodide [¹³¹I] administration in children (especially under 10 years) and adolescents are more probably compared with the adults.

(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:

Sodium iodide Na¹³¹I POLATOM, capsules for diagnostic use, are supplied in two types of immediate packages.

First type of packaging:

the polypropylene vial closed with a polyethylene stopper, placed in a shielding lead container. Single vial may contain up to 10 capsules of the same radioactivity. Each box is accompanied by a radioactive source certificate.

Second type of packaging:

the polypropylene vial closed with a polypropylene stopper containing iodine absorber and placed in a shielding lead container. The package contains a single capsule. Each box is accompanied by a separate polypropylene applicator for capsule administration and radioactive source certificate.

Marketing authorization:

Poland: Jodek sodu Na¹³¹I POLATOM kapsułki do diagnostyki

Belarus: НАТРИЯ ЙОДИД Na¹³¹I ПОЛАТОМ капсулы для диагностики

Colombia: Yoduro sodico-131 capsulas

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Sodium iodide Na¹³¹I

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

Natrii iodidi (¹³¹I) capsulae ad usum therapeuticum

code: MI-4T

■ Qualitative and quantitative composition:

Single hard capsule contains sodium iodide (¹³¹I) in the radioactivity range [37-5500 MBq].

■ 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.
- ▶ for the thyroid residue ablation after surgery of differentiated thyroid tumors and in the treatment of iodine-accumulating metastases.

■ Posology and method of administration:

Sodium iodide Na¹³¹I 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.

Pediatric population:

The use of radioiodine in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activity to be administered to children and adolescents should be a fraction of the adult dose calculated according to child body weight/age.

(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:

Gelatin capsules for therapeutic use are provided in the two types of direct packaging:

the polyethylene vial closed with a polyethylene stopper containing iodine absorber and placed in a shielding lead container. The package contains a single capsule. Each box is accompanied by a separate polypropylene applicator (type A) for capsule administration and radioactive source certificate.

or

the polypropylene vial closed with a polypropylene stopper containing iodine absorber and placed in a shielding lead container. The package contains a single capsule. Each box is accompanied by a separate polypropylene applicator (type B) for capsule administration and radioactive source certificate.

Marketing authorization:

Poland: Jodek sodu Na¹³¹I POLATOM kapsułki do terapii

Belarus: НАТРИЯ ЙОДИД Na¹³¹I ПОЛАТОМ капсулы для терапии

Colombia: Yoduro sodico-131 capsulas

Costa Rica: Yoduro de sodio Na¹³¹I POLATOM capsulas

Georgia: Sodium iodide Na¹³¹I POLATOM, capsules for therapeutic use

Greece: Thyrocap

South Korea: Thyrokey P therapeutic sodium iodide (I-131) capsule

Ukraine: НАТРІЮ ЙОДИД Na¹³¹I ПОЛАТОМ

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Iodopol

hard capsules, 37-7400 MBq

Sodium iodide (^{131}I)

code: MI-4T

■ Qualitative and quantitative composition:

One capsule contains sodium iodide (^{131}I)
37 - 7400 MBq at time of calibration.

■ Excipients:

One hard capsule contains maximum 97 mg sodium per capsule.

One hard capsule contains quinolone yellow (E 104) 0.2% per capsule shell.

Capsule contents: sodium carbonate, sodium hydrogen carbonate, sodium hydroxide, disodium phosphate dihydrate, sodium thiosulfate.

Gelatin capsule shell composition: quinoline yellow (E 104), erythrosine (E 127), titanium dioxide (E 171), gelatin.

■ Indications:

Radioiodide thyroid therapy is indicated in adults and children for:

- ▶ Hyperthyroidism: treatment of Graves' disease, toxic multinodular goitre or autonomous nodules.
- ▶ Treatment of large euthyroid (nontoxic) goitre.
- ▶ Treatment of papillary and follicular thyroid carcinoma, including metastatic disease.

Sodium iodide (^{131}I) therapy is often combined with surgical intervention and with antithyroid medicinal products.

■ Posology and method of administration:

This medicinal product should be administered only by authorised healthcare professionals in designated clinical settings.

The activity to be administered is a matter for clinical judgement. The therapeutic effect is only achieved after several weeks. The activity of the capsule should be determined before use.

Radiopharmaceuticals should be received, used and administered only by authorized persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organization.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements.

(for detailed information see SmPC)

■ Calibration:

7 days

■ Radionuclidic purity:

$\geq 99,9\%$

■ Radiochemical purity:

$\geq 95\%$

■ Expiration:

21 days from the date of manufacture

■ Storage:

in the original package, below 25°C

■ Package:

The polypropylene vial placed in a shielding lead container, closed with a lead stopper which contains polypropylene insert with iodine absorber. The package contains a single capsule. Each package is accompanied by a separate polypropylene applicator for capsule administration.



Marketing authorization:

Poland:	Iodopol
Austria:	Iodopol 37-7400 MBq Hartkapsel
Bulgaria:	Iodopol
Czech Rep.:	Iodopol
Estonia:	IODOPOL
Lithuania:	Sodium iodide (^{131}I) POLATOM 37-7400 MBq kietosios kapsules
Slovakia:	Iodopol
Slovenia:	Natrii iodidum (^{131}I) POLATOM 37-7400 MBq trda kapsula

Contact:

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

Sodium iodide Na¹³¹I

solution for injection

Natrii Iodidi (¹³¹I) solutio

code: MI-2

■ Qualitative and quantitative composition:

One milliliter of solution contains sodium iodide [¹³¹I] Natrii iodidi (131I) in the following activities range [37 - 740 MBq]

■ Excipients:

Sodium carbonate, sodium hydrogen carbonate, sodium thiosulphate pentahydrate, sodium chloride, water for injection

■ Indications:

The medicinal product is used:

- ▶ in the diagnosis 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 the normal thyroid parenchyma) nodules.
- ▶ to study radioiodine location in thyroid tissue
- ▶ an estimation of the thyroid uptake and the iodine effective half-life can be used to calculate the dose of radioiodine planned for therapy.
- ▶ in the management of patients with differentiated thyroid carcinoma in order to identify the remaining thyroid tissue after surgery and in the diagnostics of metastases.
- ▶ in the treatment of benign thyroid diseases: thyroid nodular goitre, hyperthyroidism in the Graves-Basedow's disease, autonomic nodule, the toxic multinodular goiter, differentiated thyroid cancer, for the thyroid residue ablation after surgery and in the treatment of iodine-accumulating metastases.

■ Posology and method of administration:

Sodium iodide Na¹³¹I, solution for injection is a medicinal product for intravenous administration. The product is intended for the direct administration to patients at various doses of radioactivity, depending on the indication.

The recommended diagnostic activities:

- for the scintigraphic thyroid diagnosis in benign disease and for the kinetic studies of thyroid uptake: 0.15 - 4 MBq of sodium iodide [¹³¹I] 24 hours prior the examination.
- for diagnostics in patients treated for differentiated thyroid carcinoma (for metastases and for thyroid remnant identification): 37-240 MBq (usually 37-74 MBq) of sodium iodide [¹³¹I].

The recommended treatment activities:

Adults

Treatment of hyperthyroidism and nodular goitre: the activity administered is usually in the range of 200 - 800 MBq but repeated treatment may be necessary.

The required therapeutic dose depends on the diagnosis, the size of lesion or the gland, thyroid uptake and the effective half-life of iodine [¹³¹I] in the lesion or in the thyroid. Patients should be rendered euthyroid medically whenever possible before giving radioiodine treatment for hyperthyroidism.

For thyroid ablation and treatment of metastases: the administered activity doses of sodium iodide [¹³¹I] following total or subtotal thyroidectomy to ablate remaining thyroid tissue is in the range of 1850 - 3700 MBq. It depends on the remnant size and radioiodine uptake. In subsequent treatment for metastases, administered activity is in the range 3700 - 11 100 MBq.

Pediatric population:

The use of radioiodine in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activity to be administered to children and adolescents should be a fraction of the adult dose calculated according to child body weight/age. There should be borne in mind that the late undesirable effects connected with sodium iodide [¹³¹I] administration in children (especially under 10 years) and adolescents are more probably compared with the adults.

(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 Na¹³¹I
roztwór do wstrzykiwań

Colombia: Yoduro de sodio, Na¹³¹I,
solucion inyectable

Russia: Натрия иодид Na¹³¹I

Ukraine: НАТРІЮ ЙОДИД Na¹³¹I
ДЛЯ ІН'ЄКЦІЙ

Contact:

Export Department +48 22 273 1820

email: polatom@polatom.pl

Strontium chloride $^{89}\text{SrCl}_2$ solution for injection

Stronti (^{89}Sr) chloridi solutio iniectionabilis

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 $^{89}\text{SrCl}_2$ 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 $^{89}\text{SrCl}_2$ 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:

≥ 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 $^{89}\text{SrCl}_2$ POLATOM

Belarus: СТРОНЦИЯ ХЛОРИД $^{89}\text{SrCl}_2$
ПОЛАТОМ

Ukraine: СТРОНЦІЮ ХЛОРИД $^{89}\text{SrCl}_2$
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:

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

other γ impurities $\leq 0.01\%$

■ Chemical impurities:

Cu, Zn, Co, Ni, Fe, Pb (single impurity $\leq 0.1 \mu\text{g}/\text{GBq}$)

■ 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 colour 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:

$^{177\text{m}}\text{Lu} \leq 0.05\%$

other γ impurities $\leq 0.01\%$

■ Chemical impurities:

Cu, Zn, Co, Ni, Fe, Pb (single impurity $\leq 0.1 \mu\text{g/GBq}$)

■ Expiration:

7 days from the date of manufacture

■ Storage:

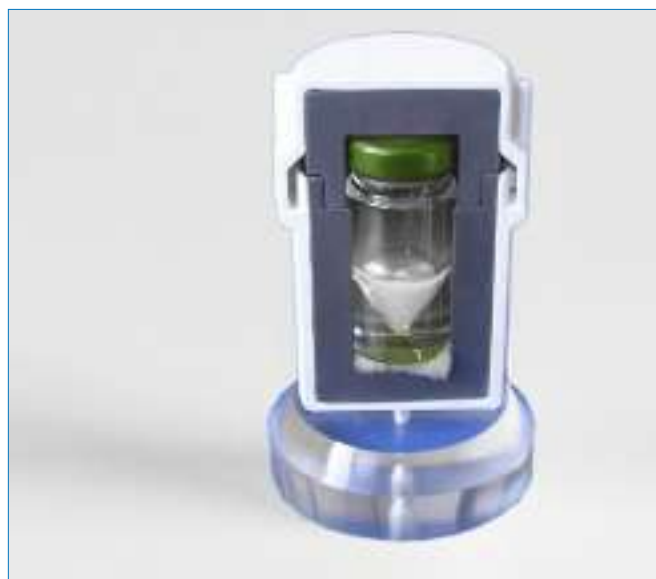
In the original package, below 25°C

■ 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 ionizing 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 - API grade	DOTATATE 0.25 mg	DOTATATE 0.1 mg	DOTATATE 1.0 mg
Code	DOT-03	DOT-04	DOT-05
Purpose	Peptide for radiolabelling, e.g. with ^{68}Ga , ^{177}Lu , ^{90}Y . The labelling must be performed in the buffer that the recipient must independently prepare.		

GMP - compliant	Code	Purpose
DOTATATE SA 50 µg kit for direct ^{68}Ga radiolabelling	DOT-06	for ^{68}Ga labelling (5 mL of $^{68}\text{GaCl}_3$ in 0.1M HCl)
DOTATATE SA 40 µg kit for direct ^{68}Ga radiolabelling	DOT-07	for ^{68}Ga labelling (4 mL of $^{68}\text{GaCl}_3$ in 0.05M HCl)
PSMA-11 1.0 mg	PMA-00	for ^{68}Ga labelling
PSMA-11 kit for ^{68}Ga labelling	PMA-01	for ^{68}Ga labelling (when eluted with 0.05 M ÷ 0.1 M HCL)
PSMA-D4 100 µg kit for direct ^{177}Lu radiolabeling	PMA-03	for ^{177}Lu labelling in accordance with procedure of labelling issued by POLATOM
PSMA-D4 100 µg	PMA-04	for ^{177}Lu labelling in accordance with procedure of labelling issued by POLATOM
PSMA-HYNIC- 23 µg	TCP-01	for <i>direct</i> preparation of $^{99\text{m}}\text{Tc}$ -PSMA-HYNIC without necessity of purification step. Radiochemical purity >90%
Ascorbic acid 50 mg	ASC-01	preparation of buffer solution for ^{90}Y or ^{177}Lu 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-life ($T_{1/2}$): 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

¹³¹I decay

The half-life ($T_{1/2}$): 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 μ Ci
1GBq	= 27.027 mCi
1TBq	= 27.027 Ci

Curie in Becquerel:

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

Rad in Gray:

1mRad	= 10 μ Gy
1Rad	= 10 mGy

Gray in Rad:

1mGy	= 100 mRad
1Gy	= 100 Rad

Rem in Sievert:

1mRem	= 10 μ Sv
1Rem	= 10 mSv

Sievert in Rem:

1mSv	= 100 mRem
1Sv	= 100 Rem





2021



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