SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium iodide Na^{131}I POLATOM, capsules for diagnostic use Hard capsules, 1-37 MBq

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Single hard capsule contains sodium iodide [^{131}I] *Natrii iodidi* (^{131}I) in the radioactivity range [1-37 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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Hard capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
This medicinal product is for diagnostic use only.
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.
Sodium iodide Na^{131}I POLATOM, capsules for diagnostic use may be used 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.
Sodium iodide Na^{131}I POLATOM, capsules for diagnostic use is also used in the management of patients with differentiated thyroid carcinoma to identify the remaining thyroid tissue and in the metastases diagnostics.

4.2 Posology and method of administration
Sodium iodide Na^{131}I POLATOM, capsules for diagnostic use is a medicinal product for oral administration.
The recommended activities for an adult patient (70 kg) are as follows:
- for the scyntygraphic thyroid diagnosis and thyroid uptake studies: 0.15-4 MBq of sodium iodide (^{131}I) 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 [^{131}I]. The whole body scintigraphy is usually conducted 72 hours (or more) after sodium iodide [^{131}I] administration.

In light of the European Directive 97/43/Euratom and current practice throughout Europe, the above activities should be considered only as a general indication. It should be noted that in each country nuclear medicine physicians should respect the diagnostic reference levels (DRL) and the rules laid down by the local legislation. The administration of activities greater than local DRLs should be justified.
The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Paediatric 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 udesirable effects connected with sodium iodide [^{131}I] administration in children (esspecialy under 10 years) and adolescents are more probably compared with the adults.
The diagnostic activities to be administered to children should be a fraction of the adult dose calculated from the body weight/surface area methods according to the following equations:

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq) x child weight (kg)}}{70\ \text{kg}}$$

$$\text{Paediatric dose (MBq)} = \frac{\text{Adult dose (MBq) x child surface (m}^2\text{)}}{1.73}$$

Correction factors given for guidance are proposed below (in accordance with Paediatric Task Group of European Association of Nuclear Medicines recommendations)

Fraction of adult dose				
3 kg = 0.1		22 kg = 0.50		42 kg = 0.78
4 kg = 0.14		24 kg = 0.53		44 kg = 0.80
6 kg = 0.19		26 kg = 0.56		46 kg = 0.82
8 kg = 0.23		28 kg = 0.58		48 kg = 0.85
10 kg = 0.27		30 kg = 0.62		50 kg = 0.88
12 kg = 0.32		32 kg = 0.65		52-54 kg = 0.90
14 kg = 0.36		34 kg = 0.68		56-58 kg = 0.92
16 kg = 0.40		36 kg = 0.71		60-62 kg = 0.96
18 kg = 0.44		38 kg = 0.73		64-66 kg = 0.98
20 kg = 0.46		40 kg = 0.76		68 kg = 0.99

4.3 Contraindications
Sodium iodide Na^{131}I POLATOM, capsules for diagnostic use must not be used in the following cases:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- In women with established or suspected pregnancy or when pregnancy has not been excluded (see section 4.6).
- Breast-feeding women

Sodium iodide Na^{131}I POLATOM, capsules for diagnostic use should not be used in the following cases:
- For diagnostic purposes in children under 10 years of age.
- Thyroid scintigraphy except in the follow-up of malignant disease or when iodine-123 or technetium-99m is not available.

4.4 Special warnings and precautions for use
Individual benefit/risk justification
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.
The possibility of hypersensitivity including serious anaphylactic/anaphylactoid reactions after sodium iodide [^{131}I] administration is very low. These reactions should always be considered and advanced life support facilities should be readily available.
Suitable precautions should be taken after sodium iodide [^{131}I] administration in order to avoid any contamination.
There is no evidence of an increased incidence of malignancies (cancer, leukaemia or mutations) in patients treated for diagnostic purpose with sodium iodide [^{131}I].
The special care should be taken in patients with swallowing disorders or gastrointestinal diseases. The capsules should be swallowed whole with sufficient fluid to ensure clear passage into the stomach and upper small intestine. Concomitant use of H_2 antagonists or proton pump inhibitors is advised.

Renal impairment
In patients with reduced kidney function, careful consideration of the indication is required since an increased radiation exposure is possible in these patients.

Pregnancy
Pregnancy, see section 4.6.

Paediatric population
For information on the use in paediatric population, see section 4.2.

Patient preparation
The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the study in order to reduce radiation.
Due to reduced iodide [^{131}I] uptake in the presence of food in the stomach, it is recommended to keep the patient fasted for approximately 2 hours before and after swallowing the capsule containing sodium iodide [^{131}I], for better thyroid uptake.
A low iodine diet (especially in patients prior to therapy for thyroid carcinoma) is recommended. This will enhance iodide [^{131}I] uptake into functioning thyroid tissue.

After the procedure
Due to retention of iodide [^{131}I] in patient body after capsule administration, it is recommended to avoid close contact between patient and other people (especially children and pregnant women) for the period defined in appropriate regulations.

Specific warnings
This medicinal product contains from 80 to 96 mg of sodium in each capsule. This should be taken into account in patients on a low sodium diet.
In patients with a known hypersensitivity for gelatine or their metabolites, sodium iodide [^{131}I] solution should be preferred.

4.5 Interactions with other medicinal products and other forms of interaction
Many pharmacological agents are known to interact with iodide. These may do so by a variety of mechanisms which can affect the binding of iodides to proteins or pharmacokinetics of labelled iodide. It is therefore necessary to take a full drug history and ascertain whether any medications are required to be withheld prior to the administration of sodium iodide [^{131}I].
For example, the treatment with the following substances should be discontinued:

Active substances	Period of rest before administration of sodium iodide [^{131}I]
Antithyroid agents (e.g. carbimazole, methimazole, propylura-cil), perchlorate	2–5 days before administration
Salicylates, steroids, sodium nitroprusside, nitrates, sodium sulfobromophthalein, anti-coagulants, antihistamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiocyanate, thiopental	1 week
Phenylbutazone	1-2 weeks
Iodine-containing expectorants and vitamins	4 weeks
Liothyronine	2 weeks
Levothyroxine	4 weeks
Amiodarone	3-6 months
Iodine-containing preparations for topical use	1-9 months
Water-soluble iodine-containing contrast media	1–2 months
Lipophilic iodine-containing contrast media	3–6 months

4.6 Fertility, pregnancy and lactation
Women of childbearing potential
When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy
Sodium iodide [^{131}I] is contraindicated during established or suspected pregnancy or when pregnancy has not been excluded (the absorbed dose to the uterus is likely to be in the range 0.01-22 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters).

Breast-feeding
Before administering a radioactive medicinal product to a mother who is breast-feeding consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast-feeding and as to whether the most appropriate choice of radiopharmaceutical has been made. If the administration is considered necessary, breast-feeding should be interrupted indefinitely after sodium iodide [^{131}I] administration.

4.7 Effects on the ability to drive and use machines
No data.

4.8. Undesirable effects
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.
The frequencies of undesirable effects after product administration are presented in the table below:

Immune system disorders Hypersensitivity	Frequency not known (cannot be estimated from the available data)
Gastrointestinal disorders Nausea, vomiting	Frequency not known (cannot be estimated from the available data)
Congenital, familial and genetic disorders Congenital thyroid disorders	Frequency not known (cannot be estimated from the available data)

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations the current evidence suggests that these adverse reactions are expected to occur with a low probability.
For most diagnostic investigations using a nuclear medicine procedure the radiation dose delivered (effective dose/EDE) is less than 20 mSv. For sodium iodide [^{131}I], whose activity is 1-37 MBq, this level is usually slightly higher.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

Adverse reactions may be reported to Marketing Authorisation Holder.

4.9 Overdose
This product is supplied as a capsule of known radioactivity, what facilitates control of the dose administered to the patient. The personnel performing studies with radiopharmaceuticals may be obliged to measure their activity before each administration in accordance with local regulations, what additionally reduces the risk of sodium iodide [^{131}I] overdose.

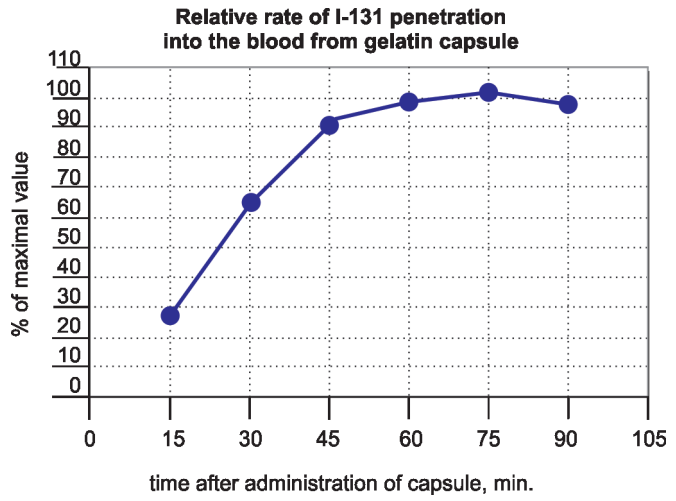
In the event of administration of a radiation overdose, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. High radiation exposure through sodium iodide [^{131}I] overdose can be also reduced by the use of emetics and by the administration of thyroid blocking agents, such as potassium perchlorate or preparation containing stable iodine (I-127).

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: various thyroid diagnostic radiopharmaceuticals, sodium iodide [^{131}I]
ATC Code: V09FX03
Sodium iodide [^{131}I], in the amount used for diagnostic indications, is not known to have any pharmacological effect.

5.2 Pharmacokinetic properties
After oral administration sodium iodide [^{131}I] is absorbed rapidly from the upper gastrointestinal tract (90% in 60 minutes). The pharmacokinetics follows that of unlabelled iodine. After entering the bloodstream it is distributed in the extra thyroidal compartment. From here it is predominantly taken up by the thyroid or excreted renally. Small amounts of sodium iodide [^{131}I] are taken up by salivary glands, gastric mucosa and would also be localised in breast milk, the placenta and choroid plexus.

The effective half-life of radioiodine in plasma is about 12 hours whereas that for radioiodine taken by the thyroid gland is about 6 days. Thus, after administration of sodium iodide [^{131}I], approximately 40% of the activity has an effective half-life of 0.4 days and the remaining 60%, 8 days. Urinary excretion is 37-75%; faecal excretion is about 10% with almost negligible excretion in sweat.

The ion $^{131}I^-$ accumulates in the thyroid due to active transportation through the gland's cell membranes. Iodide is then oxidized in the thyroid into iodine and incorporated into thyroglobulin thyrosyl residues. Under normal conditions, every hour approximately 2% of free circulating radioactive iodine is absorbed in the thyroid gland.



5.3 Preclinical safety data

Because of the small quantities of substance administered compared with the normal food intake of iodine (40-500 µg/day) no acute toxicity is expected or observed.
There are no data available neither on the toxicity of repeated doses of sodium iodide [^{131}I] or on its effects on reproduction in animals or its mutagenic or carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate
Sodium hydrogen carbonate
Disodium hydrogen phosphate dihydrate
Sodium thiosulphate pentahydrate
Hard gelatin capsule

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

21 days from the production date.

6.4 Special precautions for storage

Store below 25°C.
Store in original shielding lead container.
Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

6.5 Nature and contents of container

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

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.

6.6 Special precautions for disposal

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 licenses of the competent official organization.
Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements.
The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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Phone: +48 22 7180700
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8. MARKETING AUTHORISATION NUMBER

19004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 27.07.1984
Date of latest renewal: 29.07.2013

10. DATE OF REVISION OF THE TEXT

12.01.2015

11. DOSIMETRY

Iodine ^{131}I decays by emitting beta radiation of maximal energy 606 keV and gamma radiation with the most significant gamma photon of energy 365 keV. Iodine-131 has a half-life of 8.02 days.
The radioactive dose absorbed by a patient depends on the ability of the thyroid gland to take up iodine.
The ICRP (International Commission on Radiological Protection) model refers to intravenous administration. Since absorption of radioiodide is rapid and complete, this model is applicable in case of oral administration also but there is a further radiation dose to the stomach wall in addition to that due to gastric and salivary secretion. Assuming that the mean residence time in the stomach is 0.5 h, after oral administration the absorbed dose to the stomach wall increase by about 30% for ^{131}I when compared with intravenous model. Changes to other organs and tissues absorbed doses are very small.
The model for the case of a blocked thyroid is the same as that above, except that there is no specific uptake in any organ or tissue. A uniform distribution is assumed, together with an excretion half-time of 8 h.
For a 55% thyroid uptake of ^{131}I, the effects of circulating organic iodine and recycled iodide are to increase the self doses to body organs other than thyroid, GI tract and bladder.
Radiation dose to specific organs, which may not be the target organ, can be influenced significantly by pathophysiological changes induced by the disease process.
Tabulated radiation dosimetry according to the Publication 53 of the ICRP, Radiation Dose to Patients from Radiopharmaceuticals, Pergamon Press 1987, Vol. 18 No. 1-4, 1987, p. 259-278.

Organ	Absorbed dose per unit activity administered [mGy/MBq] Thyroid blocked, uptake 0%				
	Adult	15 years	10 years	5 years	1 year
Adrenals	0.037	0.042	0.067	0.110	0.200
Bladder wall	0.610	0.750	1.100	1.800	3.400
Bone surfaces	0.032	0.038	0.061	0.097	0.190
Breast	0.033	0.033	0.052	0.085	0.170
GI-tract					
Stomach wall	0.034	0.040	0.064	0.100	0.190
Small intest	0.038	0.047	0.075	0.120	0.220
ULI wall	0.037	0.045	0.070	0.120	0.210
LLI wall	0.043	0.052	0.082	0.130	0.230
Kidneys	0.065	0.080	0.120	0.170	0.310
Liver	0.033	0.040	0.065	0.100	0.200
Lungs	0.031	0.038	0.060	0.096	0.190
Ovaries	0.042	0.054	0.084	0.130	0.240
Pancreas	0.035	0.043	0.069	0.110	0.210
Red marrow	0.035	0.042	0.065	0.100	0.190
Spleen	0.034	0.040	0.065	0.100	0.200
Testes	0.037	0.045	0.075	0.120	0.230
Thyroid	0.029	0.038	0.063	0.100	0.200
Uterus	0.054	0.067	0.110	0.170	0.300
Other tissue	0.032	0.039	0.062	0.100	0.190
Effective dose [mSv/MBq]	**0.072**	**0.088**	**0.140**	**0.210**	**0.400**
Bladder wall contributes to 50.8% of the effective dose. **Incomplete blockage:** Effective dose [mSv/MBq] at small uptake in the thyroid:					
uptake 0.5%	0.300	0.450	0.690	1.500	2.800
uptake 1.0%	0.520	0.810	1.200	2.700	5.300
uptake 2.0%	0.970	1.500	2.400	5.300	10.00

Organ	Absorbed dose per unit activity administered [mGy/MBq] Thyroid uptake 15%				
	Adult	15 years	10 years	5 years	1 year
Adrenals	0.036	0.043	0.071	0.110	0.220
Bladder wall	0.520	0.640	0.980	1.500	2.900
Bone surfaces	0.047	0.067	0.094	0.140	0.240
Breast	0.043	0.043	0.081	0.130	0.250
GI-tract					
Stomach wall	0.460	0.580	0.840	1.500	2.900
Small intest	0.280	0.350	0.620	1.000	2.000
ULI wall	0.059	0.065	0.100	0.160	0.280
LLI wall	0.042	0.053	0.082	0.130	0.230
Kidneys	0.060	0.075	0.110	0.170	0.290
Liver	0.032	0.041	0.068	0.110	0.220
Lungs	0.053	0.071	0.120	0.190	0.330
Ovaries	0.043	0.059	0.092	0.140	0.260
Pancreas	0.052	0.062	0.100	0.150	0.270
Red marrow	0.054	0.074	0.099	0.140	0.240
Spleen	0.042	0.051	0.081	0.120	0.230
Testes	0.028	0.035	0.058	0.094	0.180
Thyroid	210.0	340.0	510.0	1100.0	2000.0
Uterus	0.054	0.068	0.110	0.170	0.310
Other tissue	0.065	0.089	0.140	0.220	0.400
Effective dose [mSv/MBq]	**6.600**	**10.00**	**15.00**	**34.00**	**62.00**

Organ	Absorbed dose per unit activity administered [mGy/MBq] Thyroid uptake 35%				
	Adult	15 years	10 years	5 years	1 year
Adrenals	0.042	0.050	0.087	0.140	0.280
Bladder wall	0.400	0.500	0.760	1.200	2.300
Bone surfaces	0.076	0.120	0.160	0.230	0.350
Breast	0.067	0.066	0.130	0.220	0.400
GI-tract					
Stomach wall	0.460	0.590	0.850	1.500	3.000
Small intest	0.280	0.350	0.620	1.000	2.000
ULI wall	0.058	0.065	0.100	0.170	0.300
LLI wall	0.040	0.051	0.080	0.130	0.240
Kidneys	0.056	0.072	0.110	0.170	0.290
Liver	0.037	0.049	0.082	0.140	0.270
Lungs	0.090	0.120	0.210	0.330	0.560
Ovaries	0.042	0.057	0.090	0.140	0.270
Pancreas	0.054	0.069	0.110	0.180	0.320
Red marrow	0.086	0.120	0.160	0.220	0.350
Spleen	0.046	0.059	0.096	0.150	0.280
Testes	0.026	0.032	0.054	0.089	0.180
Thyroid	500.0	790.0	1200.0	2600.0	4700.0
Uterus	0.050	0.063	0.100	0.160	0.300
Other tissue	0.110	0.160	0.260	0.410	0.710
Effective dose [mSv/MBq]	**15.00**	**24.00**	**36.00**	**78.00**	**140.00**

Organ	Absorbed dose per unit activity administered [mGy/MBq] Thyroid uptake 55%				
	Adult	15 years	10 years	5 years	1 year
Adrenals	0.049	0.058	0.110	0.170	0.340
Bladder wall	0.290	0.360	0.540	0.850	1.600
Bone surfaces	0.110	0.170	0.220	0.320	0.480
Breast	0.091	0.089	0.190	0.310	0.560
GI-tract					
Stomach wall	0.460	0.590	0.860	1.500	3.000
Small intest	0.280	0.350	0.620	1.000	2.000
ULI wall	0.058	0.067	0.110	0.180	0.320
LLI wall	0.039	0.049	0.078	0.130	0.240
Kidneys	0.051	0.068	0.100	0.170	0.290
Liver	0.043	0.058	0.097	0.170	0.330
Lungs	0.130	0.180	0.300	0.480	0.800
Ovaries	0.041	0.056	0.090	0.150	0.270
Pancreas	0.058	0.076	0.130	0.210	0.380
Red marrow	0.120	0.180	0.220	0.290	0.460
Spleen	0.051	0.068	0.110	0.170	0.330
Testes	0.026	0.031	0.052	0.087	0.170
Thyroid	790.0	1200.0	1900.0	4100.0	7400.0
Uterus	0.046	0.060	0.099	0.160	0.300
Other tissue	0.160	0.240	0.370	0.590	1.000
Effective dose [mSv/MBq]	**24.00**	**37.00**	**56.00**	**120.00**	**220.00**

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

This product is supplied as a capsule of known radioactivity (the activity is determined at 12^{oo} on the day of calibration).
Regulations for safety of work at exposure to ionising radiation should be strictly observed during administration of radiopharmaceutical.

Instructions for opening the container with the radioactive product:
First type of container:
1. Check the radioactivity and calibration date placed on the outer package.
2. Tear off the upper cover of the shipping container (metal tin).
3. Remove the upper styrofoam inlay.
4. Take the capsule shielding container out.
5. Remove the upper cover of the capsule shielding container.
6. Remove the plastic cap from the polypropylene vial inside the lead container.
7. Using a tweezers, take out the capsules separately from the vial.

Second type of container:
1. Check the radioactivity and calibration date placed on the outer package.
2. Tear off the upper cover of the shipping container (metal tin).
3. Remove the upper styrofoam inlay.
4. Take the capsule shielding container out.
5. Tear the paper-foil mouthpiece wrapping and take out the mouthpiece.
6. Open the capsule shielding container. To do this, hold the bottom part of the container and pull the upper part upwards. The vial containing the capsule should remain in the shielding container.
7. Connect the mouthpiece to the vial. To do this, screw in the mouthpiece into the vial containing the capsule.
8. During the administration of the capsule it is recommended to keep the vial containing the capsule in the shielding container. The patient holding the shielding container in his hand takes the mouthpiece in his mouth and then tilts it to get the capsule from the vial through the mouthpiece. When required, it is possible to administer a capsule without using the shielding container. The patient grasps the mouthpiece, takes the capsule vial out from the shielding container, takes the mouthpiece in his mouth and then tilts it to get the capsule from the vial through the mouthpiece.
9. After the administration of the capsule, the mouthpiece and the vial should be disposed of. The shielding container should be returned to the manufacturer.

To disconnect the mouthpiece from the vial, put the vial with the mouthpiece in the shielding container, and then holding the container with your hand screw off the mouthpiece in order to disconnect it.

In order to measure the capsule activity, take the mouthpiece fixed to the capsule vial with the gripping device of the dose calibrator and load in the dose calibrator. When the measurement is finished remove the mouthpiece fixed to the capsule vial and place it back in the shielding container. When transferring the capsule to another room is necessary, the mouthpiece should be disconnected from the vial according to above instruction. After disconnecting the mouthpiece, cover the shielding container with a lid.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

POLATOM