Radiation dose to specific organs, which may not be the target organ of therapy, can be influenced significantly by pathophysiological changes induced by the disease process.
As part of the risk-benefit assessment it is advised that the effective dose equivalent and likely radiation doses to individual target organ(s) be calculated prior to administration. The activity might then be adjusted according to thyroid mass, biological half-life and the "re-cycling" factor which take into account the physiological status of the patient (including iodine depletion) and the underlying pathology.
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 ready to use solution of known radioactivity.
Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.
The vials must not be opened before disinfecting the stopper, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorized automated application system.
If the integrity of this vial is compromised, the product should not be used.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

POLATOM

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium iodide $Na^{131}I$, solution for injection

Solution for injection, 37-740 MBq/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One mililiter of solution contains sodium iodide [^{131}I] *Natrii iodidi (^{131}I)* in the following activities range [37 - 740 MBq]
Iodine-131 is obtained by neutron irradiation of tellurium oxide 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 radiation of 365 keV (81.7%), 637 keV (7.2%) and 284 keV (6.1%) and beta radiation of maximum energy of 606 keV.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection.
Clear colourless solution.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
The medicinal product is both for diagnostic and therapeutic use.
The 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. Sodium iodide [^{131}I] may be used 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.

Sodium iodide [^{131}I] is also used 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.

This product is used in the treatment of benign thyroid diseases: thyroid nodular goitre, hyperthyroidism in the Graves-Basedow's disease, autonomic nodule and the toxic multinodular goitre. It is also used for treatment of differentiated thyroid cancer: for the thyroid residue ablation after surgery and in the treatment of iodine-accumulating metastases.

4.2 Posology and method of administration
Sodium iodide $Na^{131}I$, 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 dose is a matter for clinical judgement. The dose should be established individually for each patient by a nuclear medicine specialist.

The recommended diagnostic activities:
- for the scyntygraphic thyroid diagnosis in benigng disease and for the kinetic studies of thyroid uptake: 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 sodium iodide [^{131}I] administration and then again in the first few days.
- 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 [^{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 recommended therapeutic 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 [^{131}I] 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 [^{131}I] following total or sub total 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.
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. 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 udesirable effects connected with sodium iodide [^{131}I] administration in children (esspecialy under 10 years) and adolescents are more probably compared with the adults.

4.3 Contraindications
Sodium iodide $Na^{131}I$, solution for injection 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
- Breastfeeding women

Sodium iodide $Na^{131}I$, solution for injection should not be used in the following cases:
- For diagnostic purposes in children under 10 years of age.
- Thyroid scanning 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 or therapeutic effect.
The possibility of hypersensitivity including 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.
This preparation is likely to result in a relatively high radiation dose to most patients, but there is no evidence of an increased incidence of malignancies (cancer, leukaemia or mutations) in patients treated for benign thyroid disorders with sodium iodide [^{131}I].
The risk of second primary malignancies in thyroid cancer survivors treated with radioactive iodine is slightly increased compared to thyroid cancer survivors not treated with radioiodine.
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 administration of high doses of sodium iodide [^{131}I] may cause sialadenitis. There is inconclusive evidence of a beneficial effect of saliva stimulation to avoid this adverse effect.
The administration of iodine-131 in patients with active thyroid-associated ophthalmopathy (especially in smokers), can increase the ophthalmopathy. In these cases, in iodine-131 treatment period the addition of glucocortycoids or alternative therapeutic treatment should be considered.
Due to the risk of radioactive contamination the special care should be taken if iodine-131 is administered to therapy of patients:
- who may not comply with the recommendations of the medical staff
- with urinary incontinence

Renal impairment
The administration of sodium iodide [^{131}I] in patients with significant renal impairment, in which an activity adjustment is necessary, requires special attention.
Hyponatraemia
Serious manifestations of hyponatraemia have been reported after sodium iodide [^{131}I] therapy in elderly patients who have undergone total thyroidectomy. Risk factors include older age, female sex, use of thiazide diuretics and hyponatraemia at the start of sodium iodide [^{131}I] therapy. Regular serum electrolytes measurements shall be considered for these patients.
Pregnancy
Pregnancy, see section 4.6.
Paediatric population
For information on the use in paediatric population, see section 4.2.
In the treatment of children and adolescents, however, account must be taken of the greater sensitivity of a child's tissue and the greater life expectancy of such patients. The risks must also be weighed up against those of other possible treatments.
Patient preparation
A low iodine diet in patients prior to therapy will enhance [^{131}I] uptake into functioning thyroid tissue. Thyroid replacement therapy should be stopped prior

to radioiodine administration for thyroid carcinoma to ensure adequate uptake. The administration of recombinant human thyrotropin (rhTSH) is possible, for the same purpose.
Similarly, the administration of antithyroid drugs should be stopped during the treatment of hyperthyroidism with sodium iodide (^{131}I).

After the procedure
Patients exposed to high therapeutic doses of ^{131}I need to be hospitalized because of high radiological risk. The necessity of hospitalization is regulated by specified national law.
In order to reduce the absorbed radiation dose to the bladder walls (after high doses used e.g. in thyroid tumours treatment), the patient should be encouraged to increase oral fluid intake and to frequent bladder emptying.
Contraception for at least 4 months is recommended for both sexes after sodium iodide [^{131}I] therapy.
For radioprotection reasons following therapeutic doses, 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 1.2 to 1.3 mg of sodium per milliliter. This should be taken into account in patients on a low sodium diet.

4.5 Interaction 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 protein binding, the pharmacokinetics or influence the dynamic effects 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, propyluracil), perchlorate	2 – 5 days before starting diagnosis or treatment
Salicylates (large doses), steroids, sodium nitroprusside, nitrates, sodium sulfobromophthalein, oral anticoagulants, 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.
Contraception for at least 4 months is recommended for both sexes after sodium iodide [^{131}I] therapy. After the administration of higher activity of the sodium iodide [^{131}I] for diagnostic purposes in patients with differentiated thyroid carcinoma, the contraception can also be considered for a similar period of time.

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 11 - 511 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters.
Should differentiated thyroid carcinoma be diagnosed during pregnancy, radioiodine treatment should be postponed until after the pregnancy.

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

Fertility
Treatment of thyroid cancer with radioiodine may cause impairment of fertility in men and women.

4.7 Effects on 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 frequencies of undesirable effects presented in the table below are defined as follows:
Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and frequency not known (cannot be estimated from the available data).

Undesirable effects after diagnostic doses:

Immune system disorders: Frequency not known	Hypersensitivity reactions
Gastrointestinal disorders: Frequency not known	Nausea, vomiting
Congenital, familial and genetic disorders: Frequency not known	Congenital thyroid disorders

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations the current statistical evidence suggests that these adverse events are expected to occur with a low probability.

Undesirable effects after therapeutic doses:

Blood and the lymphatic system disorders Frequency not known:	Bone marrow suppression, including serious thrombocytopenia, erythrocytopenia and/or leukopenia
Eye disorders Uncommon: Frequency not known:	Sicca syndrome, acquired dacryostenosis Endocrine ophtalmopathy
Gastrointestinal disorders Very common: Rare:	Transient or persistent sialadenitis, including dry mouth, nausea Vomiting
Endocrine disorders Very common: Frequency not known:	Hypothyroidism Aggravated hyperthyroidism, Basedow's (Graves') disease, hypoparathyroidism, hyperparathyroidism
Neoplasms benign, malignant and unspecified (including cysts and polyps) Uncommon: Frequency not known:	Leukaemia Gastric cancer, bladder and breast cancer
Immune system disorders Frequency not known:	Hypersensitivity
Reproductive system and breast disorders Frequency not known:	Impairment of fertility in men and women
Congenital, familial and genetic disorders Frequency not known:	Congenital thyroid disorders
Injury, poisoning and procedural complications Very common: Rare:	Radiation injury, including radiation thyroiditis, radiation associated pain Tracheal obstruction

Early consequences
Occurrence of radiation caused pneumonia and lung fibrosis has been described in patients with lung metastases.
In the treatment of metastasizing thyroid carcinomas with central nervous system (CNS) involvement, the possibility of local cerebral oedema and/or an increasing of existing cerebral oedema must also be borne in mind.

Late consequences
Dose dependent hypothyroidism may occur as a late consequence of radioiodine treatment of hyperthyroidism. This may manifest itself weeks or years after treatment, requiring suitable timed measurement of thyroid function and appropriate thyroid replacement therapy. Hypothyroidism generally is not seen until 6 - 12 weeks after therapy.

Malfunction of the salivary and/or lacrimal glands with resulting sicca syndrome may also appear with a delay of several months and up to two years after radioiodine therapy. Epiphora due to nasolacrimal duct obstruction is mostly appearing 3 - 16 months after the radioiodine treatment. In a literature report, carcinoma of the salivary glands has been described following radioiodine-induced sialadenitis.

As a late consequence, reversible or in very rare cases irreversible bone marrow depression may develop, presenting with isolated thrombocytopenia or erythrocytopenia, which may be fatal. Bone marrow depression is more likely to occur after one single administration of more than 5000 MBq or after repeat administration in intervals below 6 months.

Radiotherapy of thyroid carcinoma can lead to an impairment of fertility in men and women. A dose-dependent, reversible impairment of spermatogenesis has been proven starting at doses of 1850 MBq; clinically relevant effects including oligospermia and azoospermia, and increased serum FSH values have been described after use of more than 3700 MBq of iodine-131.
The radiation dose resulting from therapeutic exposure may result in higher incidence of cancer and mutations. In all cases it is necessary to ensure that the risk of the radiation is less than from the disease itself.

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 solution of known radioactivity, what facilitates control of the dose administered to the patient. 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: various thyroid diagnostic radiopharmaceuticals, sodium iodide [^{131}I]
ATC code: V09FX03
Pharmacotherapeutic group: therapeutic radiopharmaceuticals, Iodine [^{131}I] compounds
ATC code: V 10X A01
Sodium iodide [^{131}I], in the amount used for both diagnostic or therapeutic indications, is not known to have any pharmacological effect.

5.2 Pharmacokinetic properties
After injection, about 20% of blood iodine is extracted in a single passage through the thyroid gland. Peak thyroid accumulation occurs within 24 - 48 hours of administration with about 50% of the maximum at 5 hours. This kinetic profile provides the rationale for the diagnostics procedures at 24 and 72 hours after administration.
Small amounts of sodium iodide [^{131}I] are taken up by salivary glands, gastric mucosa and would also be localised in the placenta and choroid plexus and secreted in breast milk. 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 ^{131}I$^-$ ion 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
Sodium thiosulphate pentahydrate
Sodium chloride
Water for injections

6.2 Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life
28 days from the production date.

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

6.5 Nature and contents of container
The 10 ml glass vial (type I) closed with a rubber stopper and aluminum cap and placed in a shielding lead container.

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. Appropriate aseptic precautions should be taken.

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

Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7
05-400 Otwock, Poland
Phone: +48 22 7180700
Fax: +48 22 7180350
e-mail: polatom@polatom.pl

8. MARKETING AUTHORISATION NUMBER

R/3271

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09.01.1978
Date of latest renewal: 29.07.2013

10. DATE OF REVISION OF THE TEXT

08.02.2018

11. DOSIMETRY

Iodine ^{131}I decays by emitting beta radiation of maximum energy of 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.
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.