SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use

Hard capsules, 37-5500 MBq

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Single hard capsule contains sodium iodide (^{131}I) *Natrii iodidi (^{131}I)* in the following activities range [37 - 5500 MBq]

Iodine-131 is produced by neutron bombardment of stable tellurium in a nuclear reactor or by fission of uranium. Iodine-131 has a half life of 8.02days. 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 product is used in the treatment of: thyroid nodular goitre, hyperthyroidism in the Graves-Basedow's disease, autonomic nodule and the toxic multinodular goitre. It is used for the thyroid residue ablation after surgery of differentiated thyroid tumours and in the treatment of iodine-accumulating metastases.

4.2 Posology and method of administration

Sodium iodide $Na^{131}I$ POLATOM, capsules for therapeutic use is a medicinal product with varying radioactivity, for oral administration.

The recommended therapeutic dose is a matter for clinical judgement. This dose should be established individually for each patient.

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 dose required depends on the diagnosis, the size of the gland, thyroid uptake and iodine clearance. Patients should be rendered euthyroid medically whenever possible before giving radioiodine treatment for hyperthyroidism.

For thyroid ablation and treatment of metastases:
The administered activities following total or sub total thyroidectomy to ablate remaining thyroid tissue are 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.

The therapeutic administration of sodium iodide (^{131}I) capsules in patients with significant renal impairment, in which an activity adjustment is necessary, requires special attention. 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 to have frequent bladder emptying.

A low iodine diet in patients prior to therapy will enhance (^{131}I) uptake into functioning thyroid tissue. It is recommended to keep the patient fasted for approximately 2 hours before and after swallowing the capsule for better thyroid uptake.

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.

The therapeutic effect is only achieved after several months.

4.3 Contraindications

Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use must not be used in the following cases:

- In women with established or suspected pregnancy or when pregnancy has not been excluded (see section 4.6).
- Breastfeeding women
- Hypersensitivity to the active substance or to any of the excipients.

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 therapeutic effect.

The special care should be taken if Sodium iodide Na^{131}I POLATOM, capsules for therapeutic use is administered to patients:

- with uncontrolled hyperthyroidism
- with swallowing disorders or gastrointestinal diseases causing regurgitation or vomiting (due to the risk of misuse and radioactive contamination, the administration of iodine-131 in other than capsules pharmaceutical form or other than oral route, should be considered).

Due to the risk of radioactive contamination the special care should be taken if iodine -131 is administered to patients:

- who may not comply with the recommendations of the medical staff
- with urinary incontinence

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.

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.

Renal impairment
The therapeutic administration of sodium iodide (^{131}I) capsules in patients with significant renal impairment, in which an activity adjustment is necessary, requires special attention.

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.

In patients with suspected gastrointestinal disease, great care should be taken when administering sodium iodide (^{131}I) capsules. 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.
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 to have frequent bladder emptying.
The oral 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.

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).
It is recommended to keep the patient fasted for approximately 2 hours before and after swallowing the capsule, for better thyroid uptake.

After the procedure
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 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 (^{131}I) iodide solution should be preferred for the radioiodine therapy.

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 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 treatment till several days after administration.
Salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, anticoagulants, antihistamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopental	1 week.
Phenylbutazone	1 - 2 weeks.
Iodine-containing expectorants and vitamins	approx. 2 weeks.
Thyroid hormone preparations	2 – 6 weeks.
Amiodarone*, benzodiazepines, lithium	approx. 4 weeks.
Iodine-containing preparations for topical use	1 - 9 months.
Iodine-containing contrast media - for intravenous use - lipophilic	 3 - 4 weeks > 1 year.

* Due to the long half-life of amiodarone, iodine uptake in the thyroid tissue can be decreased for several 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.

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.

Breast-feeding

Before administering a radioactive medicinal product to a mother who is breast-feeding consideration should be given as to whether the investigation could be reasonably delayed 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.

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

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. Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. 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.
The frequencies of undesirable effects 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)

Blood and the lymphatic system disorders Frequency not known :	Bone marrow failure, including serious thrombocytopenia, erythrocytopenia and/or leukopenia.
Eye disorders Very common: Not known:	Sicca syndrome, acquired dacryostenosis. Endocrine ophtalmopathy.
Gastrointestinal disorders Very common:	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:	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 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.

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.

4.9 Overdose
This product is supplied as a capsule of known radioactivity, what facilitates control of the dose administered to the patient. High radiation exposure through overdose can be reduced by means of administration of thyroid blocking agent, such as potassium perchlorate, the use of emetics and promoting a diuresis with frequent voiding of urine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: therapeutic radiopharmaceuticals, Iodine (^{131}I) compounds

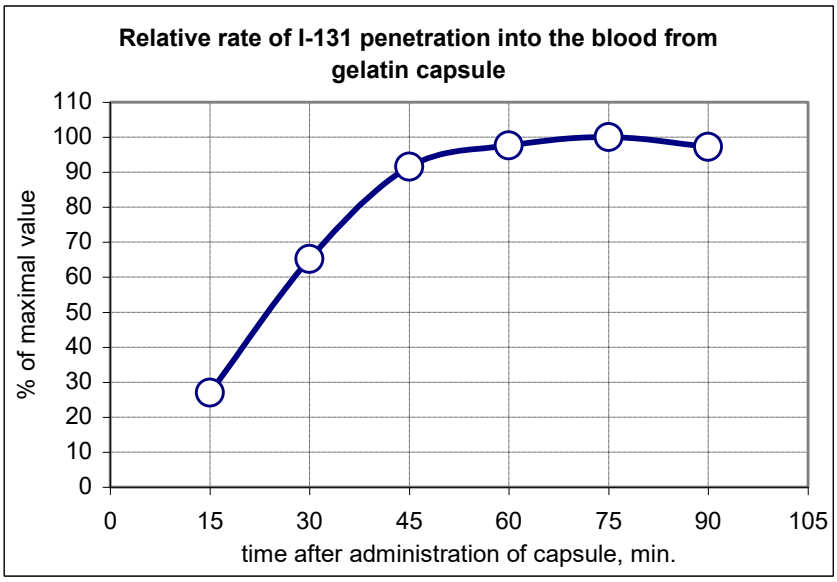
ATC code: V 10X A01

Sodium iodide (^{131}I), in the amount used for therapeutic 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 $^{131}I^-$ 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 (^{131}I) iodide 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 hydrophosphate 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

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

QUANTUM TECHNOLOGIES GLOBAL PTE. LTD.
4 CHANGI SOUTH LANE, #01-03 NAN WAH BUILDING, SINGAPORE (486127)
Contact Tel. No.: 6778 3655
Fax No.: 6777 7169
Contact Email : operations@quantumsg.com

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization:

10. DATE OF REVISION OF THE TEXT

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, and the thyroid blocking agents.
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 hr, 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 then thyroid, GI tract and bladder.
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 (EDE) 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.

Thyroid blocked, uptake 0 %

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	3.7E-02	4.2E-02	6.7E-02	1.1E-01	2.0E-01
Bladder wall	6.1E-01	7.5E-01	1.1E+00	1.8E+00	3.4E+00
Bone surfaces	3.2E-02	3.8E-02	6.1E-02	9.7E-02	1.9E-01
Breast	3.3E-02	3.3E-02	5.2E-02	8.5E-02	1.7E-01
GI-tract					
Stomach wall	3.4E-02	4.0E-02	6.4E-02	1.0E-01	1.9E-01
Small intest	3.8E-02	4.7E-02	7.5E-02	1.2E-01	2.2E-01
ULI wall	3.7E-02	4.5E-02	7.0E-02	1.2E-01	2.1E-01
LLI wall	4.3E-02	5.2E-02	8.2E-02	1.3E-01	2.3E-01
Kidneys	6.5E-02	8.0E-02	1.2E-01	1.7E-01	3.1E-01
Liver	3.3E-02	4.0E-02	6.5E-02	1.0E-01	2.0E-01
Lungs	3.1E-02	3.8E-02	6.0E-02	9.6E-02	1.9E-01
Ovaries	4.2E-02	5.4E-02	8.4E-02	1.3E-01	2.4E-01

Pancreas	3.5E-02	4.3E-02	6.9E-02	1.1E-01	2.1E-01
Red marrow	3.5E-02	4.2E-02	6.5E-02	1.0E-01	1.9E-01
Spleen	3.4E-02	4.0E-02	6.5E-02	1.0E-01	2.0E-01
Testes	3.7E-02	4.5E-02	7.5E-02	1.2E-01	2.3E-01
Thyroid	2.9E-02	3.8E-02	6.3E-02	1.0E-01	2.0E-01
Uterus	5.4 E-02	6.7E-02	1.1E-01	1.7E-01	3.0E-01
Other tissue	3.2E-02	3.9E-02	6.2E-02	1.0E-01	1.9E-01
Effective dose (mSv/MBq)	7.2E-02	8.8E-02	1.4E-01	2.1E-01	4.0E-01
Bladder wall contributes to 50.8 % of the effective dose. The effective dose to an adult administered 5.55GBq with 0 % thyroid uptake is 399.6 mSv. **Incomplete blockage:** Effective dose (mSv/MBq) at small uptake in the thyroid					
uptake 0.5 %	3.0 E-01	4.5 E-01	6.9 E-01	1.5 E+00	2.8 E+00
uptake 1.0 %	5.2 E-01	8.1 E-01	1.2 E+00	2.7 E+00	5.3 E+00
uptake 2.0 %	9.7 E-01	1.5 E+00	2.4 E+00	5.3 E+00	1.0 E+01

Thyroid uptake 15 %

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	3.6E-02	4.3E-02	7.1E-02	1.1E-01	2.2E-01
Bladder wall	5.2E-01	6.4E-01	9.8E-01	1.5E+00	2.9E+00
Bone surfaces	4.7E-02	6.7E-02	9.4E-02	1.4E-01	2.4E-01
Breast	4.3E-02	4.3E-02	8.1E-02	1.3E-01	2.5E-01
GI tract					
Stomach wall	4.6E-01	5.8E-01	8.4E-01	1.5E+00	2.9E+00
Small intest	2.8E-01	3.5E-01	6.2E-01	1.0E+00	2.0E+00
ULI wall	5.9E-02	6.5E-02	1.0E-01	1.6E-01	2.8E-01
LLI wall	4.2E-02	5.3E-02	8.2E-02	1.3E-01	2.3E-01
Kidneys	6.0E-02	7.5E-02	1.1E-01	1.7E-01	2.9E-01
Liver	3.2E-02	4.1E-02	6.8E-02	1.1E-01	2.2E-01
Lungs	5.3E-02	7.1E-02	1.2E-01	1.9E-01	3.3E-01
Ovaries	4.3E-02	5.9E-02	9.2E-02	1.4E-01	2.6E-01
Pancreas	5.2E-02	6.2E-02	1.0E-01	1.5E-01	2.7E-01
Red marrow	5.4E-02	7.4E-02	9.9E-02	1.4E-01	2.4E-01
Spleen	4.2E-02	5.1E-02	8.1E-02	1.2E-01	2.3E-01
Testes	2.8E-02	3.5E-02	5.8E-02	9.4E-02	1.8E-01
Thyroid	2.1E+02	3.4E+02	5.1E+02	1.1E+03	2.0E+03
Uterus	5.4E-02	6.8E-02	1.1E-01	1.7E-01	3.1E-01
Other tissue	6.5E-02	8.9E-02	1.4E-01	2.2E-01	4.0E-01
Effective Dose (mSv/MBq)	6.6E+00	1.0E+01	1.5E+01	3.4E+01	6.2E+01
The effective dose in an adult administered 5.55 GBq with 15 % thyroid uptake is 36,630 mSv.					

Thyroid uptake 35 %

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	15 years	10 years	5 years	1 year
Adrenals	4.2E-02	5.0E-02	8.7E-02	1.4E-01	2.8E-01
Bladder wall	4.0E-01	5.0E-01	7.6E-01	1.2E+00	2.3E+00
Bone surfaces	7.6E-02	1.2E-01	1.6E-01	2.3E-01	3.5E-01
Breast	6.7E-02	6.6E-02	1.3E-01	2.2E-01	4.0E-01
GI tract					
Stomach wall	4.6E-01	5.9E-01	8.5E-01	1.5E+00	3.0E+00
Small intest	2.8E-01	3.5E-01	6.2E-01	1.0E+00	2.0E+00
ULI wall	5.8E-02	6.5E-02	1.0E-01	1.7E-01	3.0E-01
LLI wall	4.0E-02	5.1E-02	8.0E-02	1.3E-01	2.4E-01
Kidneys	5.6E-02	7.2E-02	1.1E-01	1.7E-01	2.9E-01
Liver	3.7E-02	4.9E-02	8.2E-02	1.4E-01	2.7E-01
Lungs	9.0E-02	1.2E-01	2.1E-01	3.3E-01	5.6E-01
Ovaries	4.2E-02	5.7E-02	9.0E-02	1.4E-01	2.7E-01
Pancreas	5.4E-02	6.9E-02	1.1E-01	1.8E-01	3.2E-01
Red marrow	8.6E-02	1.2E-01	1.6E-01	2.2E-01	3.5E-01
Spleen	4.6E-02	5.9E-02	9.6E-02	1.5E-01	2.8E-01
Testes	2.6E-02	3.2E-02	5.4E-02	8.9E-02	1.8E-01
Thyroid	5.0E+02	7.9E+02	1.2E+03	2.6E+03	4.7E+03
Uterus	5.0E-02	6.3E-02	1.0E-01	1.6E-01	3.0E-01
Other tissue	1.1E-01	1.6E-01	2.6E-01	4.1E-01	7.1E-01
Effective Dose (mSv/MBq)	1.5E+01	2.4E+01	3.6E+01	7.8E+01	1.4E+02
The effective dose in an adult administered 5.55 GBq with 35 % thyroid uptake is 83,250 mSv					

Thyroid uptake 55 %

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	15 years	10 years	5 years	1 year
Adrenals	4.9E-02	5.8E-02	1.1E-01	1.7E-01	3.4E-01
Bladder wall	2.9E-01	3.6E-01	5.4E-01	8.5E-01	1.6E-00
Bone surfaces	1.1E-01	1.7E-01	2.2E-01	3.2E-01	4.8E-01
Breast	9.1E-02	8.9E-02	1.9E-01	3.1E-01	5.6E-01

GI tract					
Stomach wall	4.6E-01	5.9E-01	8.6E-01	1.5E-00	3.0E+00
Small intest	2.8E-01	3.5E-01	6.2E-01	1.0E+00	2.0E+00
ULI wall	5.8E-02	6.7E-02	1.1E-01	1.8E-01	3.2E-01
LLI wall	3.9E-02	4.9E-02	7.8E-02	1.3E-01	2.4E-01
Kidneys	5.1E-02	6.8E-02	1.0E-01	1.7E-01	2.9E-01
Liver	4.3E-02	5.8E-02	9.7E-02	1.7E-01	3.3E-01
Lungs	1.3E-01	1.8E-01	3.0E-01	4.8E-01	8.0E-01
Ovaries	4.1E-02	5.6E-02	9.0E-02	1.5E-01	2.7E-01
Pancreas	5.8E-02	7.6E-02	1.3E-01	2.1E-01	3.8E-01
Red marrow	1.2E-01	1.8E-01	2.2E-01	2.9E-01	4.6E-01
Spleen	5.1E-02	6.8E-02	1.1E-01	1.7E-01	3.3E-01
Testes	2.6E-02	3.1E-02	5.2E-02	8.7E-02	1.7E-01
Thyroid	7.9E+02	1.2E+03	1.9E+03	4.1E+03	7.4E+03
Uterus	4.6E-02	6.0E-02	9.9E-02	1.6E-01	3.0E-01
Other tissue	1.6E-01	2.4E-01	3.7E-01	5.9E-01	1.0E+00
Effective Dose (mSv/MBq)	2.4E+01	3.7E+01	5.6E+01	1.2E+02	2.2E+02
The effective dose in an adult administered 5.55 GBq with 55 % thyroid uptake is 133,2 mSv.					

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 ionizing radiation should be strictly observed during administration of radiopharmaceutical.

Instructions for opening the container with the radioactive product using the applicator:

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 shielding container containing the capsule. 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.
10. 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.

11. 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.