

TECHNICAL LEAFLET: SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

I-131-S-1.

Oral sodium iodide (¹³¹I) solution, CIS bio international.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active ingredients

Oral sodium I-131-S-1 is a sodium iodide (¹³¹I) sterile solution in a carbonate-thiosulfate buffer, with a pH in the range of 7.0 to 10.0, a specific activity equal to or greater than 185 GBq/mg on the date of calibration and a radioactive concentration of 1110 MBq/mL on the date of calibration.

Oral sodium I-131-S-1 solution contains no antimicrobial preservative.

Composition for 1 mL of carbonate-thiosulfate buffer used for the manufacture of oral sodium iodide (¹³¹I) solution :

Sodium carbonate	: 0.25 mg
Sodium bicarbonate	: 1.68 mg
Sodium thiosulfate	: 2.48 mg
Sodium hydroxide	: up to pH 8.5 - 9.5
Water for injection	: up to 1 ml

2.2 Physical characteristics

Iodine-131 is produced by fission of uranium-235 or neutron bombardment of stable tellurium in a nuclear reactor. It decays by emission of gamma radiations of 365 Kev (81%), 637 Kev (7.3%) and 284 Kev (6.0%) and beta radiations of maximal energy of 606 Kev to stable Xenon 131. Iodine-131 has a half life of 8.04 days.

Decay of iodine ¹³¹I :

Days before calibration date	- 8	- 7	- 6	- 5	- 4	- 3	- 2	- 1			
%	199.3	182.8	167.7	153.9	141.2	129.5	118.8	109.0			
Days after calibration date	0	+ 1	+ 2	+ 3	+ 4	+ 5	+ 6	+ 7	+ 8	+ 9	+ 10
%	100.0	91.7	84.2	77.2	70.8	65.0	59.6	54.7	50.2	46.0	42.2
Days after calibration date	+ 11	+ 12	+13	+ 14	+ 15	+ 16	+ 17	+ 18	+ 19	+ 20	+ 21
%	38.7	35.5	32.6	29.9	27.4	25.2	23.1	21.2	19.4	17.8	16.4

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1.1. Diagnostic indications

- Sodium iodide may be given as a "tracer" dose to study radioiodine kinetics. An estimation of the thyroid uptake and effective half life obtained with a tracer amount, can be used to calculate the activity required for radioiodine therapy.
- In the management of thyroid carcinoma, sodium iodide is used to identify thyroid remnant and metastases (after ablation).

Thyroid scanning for benign conditions with ¹³¹I can be performed but only when radiopharmaceuticals with more favourable dosimetry, eg I-123 or Tc-99m, are not available.

4.1.2 Therapeutic indications

Radioiodine thyroid therapy is indicated for :

- treatment of Graves disease, toxic multinodular goitre or autonomous nodules.
- treatment of papillary and follicular thyroid carcinoma including metastatic disease.

Sodium iodide (¹³¹I) therapy is often combined with surgical intervention and with antithyroid medications.

4.2 Posology and method of administration

Diagnostic use

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

- 1) For the thyroid uptake studies: 0.2 - 3.7 MBq.
- 2) For post thyroid ablation (for metastases and thyroid remnant): a maximum activity of 400 MBq.
- 3) For thyroid imaging: 7.4 - 11 MBq.

Scans are usually performed at 4 hours, and then again at 18-24 hours (for scintigraphy also at 72 hours).

Therapeutic use

The activity administered is a matter for clinical judgement. The therapeutic effect is only achieved after several months.

- For the treatment of hyperthyroidism

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 - 11100 MBq.

The diagnostic activity to be administered in children over 10 years old and therapeutic activity to be administered in children and adolescent should be a fraction of the adult dose calculated from the body weight/surface area methods according to the following equations :

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

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

Correction factors given for guidance are proposed below.

Fraction of adult dose

3 kg = 0.10	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

(Paediatric Task Group, EANM)

Oral solution of Sodium Iodide I-131 is administered orally by instructing the patients to drink the liquid through a straw.

In patients with suspected gastrointestinal disease, great care should be taken when administering 131-I by oral route.

After high doses used e.g. for the treatment of thyroid carcinoma, patients, should be encouraged to increase oral fluids to have frequent bladder emptying to reduce bladder radiation.

4.3 Contra-indications

- I-131 is contraindicated during pregnancy.
- I-131 is contraindicated for diagnostic purpose in children under 10 years of age.
- I-131 is contraindicated in thyroid scanning except in the follow up of malignant disease. The high radiation dose to the thyroid gland precludes its use for scanning in benign thyroid conditions, unless there are exceptional circumstances, where I-123 or Tc-99m are not available.
- I-131 by oral route is contraindicated in patients with dysphagia, oesophageal stricture, active gastritis, gastric erosions and peptic ulcer.

4.4 Special warnings and special precautions for use

This radiopharmaceutical may be received, used and administered only by authorised persons, in designated clinical setting. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the local competent official organisation.

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiological and pharmaceutical quality requirements.

This preparation is likely to result in relatively a high radiation dose to most patients (see section 4.8 and 5.4).

The administration of a high dose of radioiodine may result in significant environmental hazard. These may be of concern to the immediate family of those individual undergoing treatment or the general public depending on the level of activity administered. Suitable precautions should be taken concerning the activity eliminated by the patients in order to avoid any contaminations.

I-131 for diagnostic studies, has not to be used in children under 10 years and is not suitable for administration to children over 10 years old and adolescents unless exceptional circumstances prevail, due to significantly higher radiation exposure compared with the adult.

There is no evidence of an increased incidence of malignancies (cancer, leukemia or mutations) in man with patients treated for diagnostic purpose with Sodium Iodide I-131.

There is little evidence of an increased incidence of cancer, leukemia or mutations in man with respect to patients treated for benign thyroid disease with radioiodine, despite extensive use. In the treatment of children over 10 years old and young people however, account must be taken of the greater sensitivity of child tissue and the greater life expectancy of such patients. The risks must also be weighed up against those of other possible treatments. In the treatment of malignant thyroid disease, a higher incidence of bladder cancer has been reported in one study of patients receiving greater than 3,700 MBq I-131. Another study has reported a small excess leukemia in patients receiving very high doses. A cumulative total activity higher than 26000 MBq is therefore not advisable.

The therapeutic administration of I-131 Sodium Iodide in patients with significant renal impairment, in which an activity adjustment is necessary, requires special attention.

To avoid sialadenitis which may complicate high dose radioiodine administration, the patient may be advised to take sweets or drinks containing citric acid which will stimulate saliva excretion.

To compensate a potential transient impairment of male gonadal function by high radioiodine therapeutic dose, sperm banking should be considered for men who have extensive disease.

A low iodine diet prior to therapy will enhance uptake into functioning thyroid tissue.

Thyroid replacement should be stopped prior to radioiodine administration for thyroid carcinoma to ensure adequate uptake. A period of ten days is recommended for triiodothyronine and six weeks for thyroxine. They should be restarted two weeks after treatment. Similarly carbimazole and propylthiouracil should be stopped five days prior to treatment of hyperthyroidism and restarted several days later.

4.5 Interactions with other medicaments and other forms of interaction

Many pharmacological agents are known to interact with radioiodide. 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 I-131. For example, antithyroid agents, carbimazole (or other imidazole derivatives such as propylthiouracil), salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, perchlorate, miscellaneous agents (anticoagulants, anti-histamines, antiparasitics, penicillins, sulphonamides, tolbutamide, thiopentone), are normally withheld for 1 week ; phenylbutazone for 1-2 weeks ; expectorants, vitamins for 2 weeks ; natural or synthetic thyroid preparations (sodium thyroxine, sodium liothyronine, thyroid extract) for 2-3 weeks ; amiodarone, benzodiazepines, lithium for 4 weeks ; topical iodides for 1-9 months and for intravenous contrast agents, oral cholecystographic agents, iodine containing contrast media for a period up to 1 year.

4.6 Pregnancy and lactation

Sodium iodide I-131 is contraindicated during established or suspected pregnancy or when pregnancy has not been excluded (the absorbed dose to the uterus for this agent is likely to be in the range 11-511 mGy, and the foetal thyroid gland avidly concentrates iodine during the second and third trimesters). When it is necessary to administer radioactive medicinal product to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists it is important that radiation exposure should be the minimum consistent with achieving the desired clinical information. Alternative techniques which do not involve ionising radiation should be considered. In the case of differentiated thyroid carcinoma diagnosed in pregnancy therefore, radioiodine treatment should be postponed until after the pregnancy has ended. Women receiving Sodium Iodide-131 should be advised NOT to become pregnant within four months of administration.

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, bearing in mind the secretion activity in breast milk. Breast feeding should be discontinued indefinitely after administration of sodium iodide I-131.

4.7 Effects on ability to drive or use machines

No effects on the ability to drive or to operate machinery are to be expected after use of the drug.

4.8 Undesirable Effects

For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result.

For most diagnostic investigations using a nuclear medicine procedure the radiation dose delivered (effective dose/EDE) is less than 20 mSv. These levels are usually exceeded for this compound. The radiation dose resulting from therapeutic exposure may also result in higher incidence of cancer and mutations (see "late consequences" described below). In such cases it is necessary to ensure that the risks of the radiation are less than from the disease itself.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary effects.

The radiation dose delivered (EDE) after diagnostic and therapeutic doses of sodium iodide I-131 is higher than 20 mSv.

- Early consequences

Some cases of adverse reactions have been reported following the administration of sodium iodide I-131, including nausea, vomiting and unspecified possible allergic phenomena. Nausea and vomiting are more frequent after administration by oral route especially after therapeutic doses and the risks of contamination following the occurrence of vomiting have to be considered.

Therapeutic quantities of I-131 may worsen existing hyperthyroidism temporarily. In the course of a toxic multinodular goitre treatment, (¹³¹I) may induce Graves' disease or thyroid associated ophthalmopathy (incidence 1 to 5 %).

High levels of radioactivity may lead to gastrointestinal disturbance, usually within the first hours or days after administration. The incidence of gastrointestinal upset can be as high as 67%. This can easily be prevented or counteracted by means of symptomatic treatment.

With high dose radioiodine treatment, 1-3 days after administration, the patient may experience transient inflammatory thyroiditis and tracheitis, with a possibility of severe tracheal constriction, especially where there is existing tracheal stenosis. Sialadenitis may occur, with swelling and pain in the salivary glands, partial loss of taste and dry mouth. Incidence varies from 10% (with precautions) and 60% (without precautions). Sialadenitis is usually reversible spontaneously or with anti-inflammatory treatment but cases have occasionally been described of dose-dependent persistent loss of taste and dry mouth, followed by loss of teeth. The radiation exposure of the salivary glands should be reduced by stimulating saliva excretion with acidic substances.

Malfunction of the lachrymal glands, such as ocular dryness and nasolachrymal duct obstruction may occur after radioiodine treatment. Although these symptoms are in the majority of cases transient, they may persist for a longer period or appear late in some patients.

High levels of uptake of radioiodine given to the patients can be associated with local pain, discomfort and oedema in the tissue taking up the radionuclide.

Transient impairment of male gonadal function may occur after high radioiodine therapeutic dose or in the presence of pelvic metastasis.

In the treatment of metastasizing thyroid carcinomas with CNS involvement, the possibility of local cerebral oedema and/or an increasing existing cerebral oedema must also be born 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. The incidence of hypothyroidism, generally not seen until 6-12 weeks, following radioiodine has been variously reported as between 2-70%.

Occasionally cases of transient hypoparathyroidism have been observed after radioiodine, they must be monitored accordingly and treated with replacement therapy. As a late consequence a single administration of over 5000 MBq or in interval of below 6 months are more likely to be associated with reversible or in very rare cases irreversible bone marrow depression may develop, with isolated thrombocytopenia or erythrocytopenia, which may be fatal. Transient leucocytosis is frequently observed.

Epidemiological studies report a higher incidence of stomach cancer in patients receiving I-131.

After higher activities, typically those used in the treatment of thyroid malignancies, an increased incidence of leukemia has been observed. There may also be a small increase in bladder and breast cancers.

4.9 Overdosage

This agent is intended for use by competent personnel within a hospital setting. As such the risk of overdose is theoretical. The risks related to the inadvertent administration of excess radioactivity. High radiation exposure through overdose can be reduced by means of administration of thyroid blocking agent, such as potassium perchlorate, the use of the emetics and promoting a diuresis with frequent voiding of urine.

5. PHARMACOLOGICAL PROPERTIES

Iodide in the amount used for diagnostic and therapeutic indications, is not known to have any pharmacological effect. More than 90% of the radiation effects result from beta radiation which has a mean range of 0.5 mm.

5.2 Pharmacokinetic properties

After oral administration I-131 sodium iodide is absorbed rapidly from the upper gastrointestinal tract (90% in 60 minutes). The pharmacokinetics follow that of unlabelled iodide. After entering the blood stream it is distributed in the extra thyroidal compartment. From here it is predominantly taken up by the thyroid or excreted renally. Small amounts of I-131 iodide 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 in the order of 12 hours whereas that for radioiodine taken up by the thyroid gland is about 6 days. Thus after administration of I-131 sodium iodide 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.

5.3 Preclinical data

Because of the small quantities of substance administered compared with the normal food intake of iodine (40-500 mcg/day) no acute toxicity is expected or observed.

There are no data available on the toxicity of repeated doses of sodium iodide nor on its effects on reproduction in animals or its mutagenic or carcinogenic potential.

5.4 Radiation dosimetry

Tabulated radiation dosimetry as reported in ICRP publication n°53 (1987) are reported.

The ICRP 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 in addition to that due to gastric and salivary excretion. Assuming that the mean residence time in the stomach is 0.5 hr, the absorbed dose to the stomach increases by about 30% for I-131.

For diagnostic use

The Effective Dose Equivalent resulting from an administration activity of 400 MBq is typically between 28.8 (0% thyroid uptake) and 9,600 mSv (55% thyroid uptake).

Under similar circumstances, the dose to the thyroid will vary from 11.6 to 316,000 mGy and the dose to the bladder wall from 244 mGy to 116 mGy.

The figures quoted are on the basis of :

Thyroid mass	:	20 g
Biological half-life	:	80 days
Recycling factor	:	1.8

For therapeutic use

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 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 takes into account the physiological status of the patient (including iodine depletion) and the underlying pathology.

IODIDE Thyroid blocked, uptake 0%

¹³¹I 8.04 days

Absorbed dose per unit activity administered (mGy/MBq)					
Organ	Adult	15 year	10 year	5 year	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	5.4E-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 equivalent (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 equivalent.

Incomplete blockage:

Effective dose equivalent (mSv/MBq) at small uptake in the thyroid.

uptake: 0.5%	3.0E-01	4.5E-01	6.9E-01	1.5E+00	2.8E+00
uptake: 1.0%	5.2E-01	8.1E-01	1.2E+00	2.7E+00	5.3E+00
uptake: 2.0%	9.7E-01	1.5E+00	2.4E+00	5.3E+00	1.0E+01

Thyroid uptake 15%

Absorbed dose per unit activity administered (mGy/MBq)					
Organ	Adult	15 year	10 year	5 year	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 equivalent (mSv/MBq)	6.6E+00	1.0E+01	1.5E+01	3.4E+01	6.2E+01

Thyroid uptake 35%

Absorbed dose per unit activity administered (mGy/MBq)					
Organ	Adult	15 year	10 year	5 year	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 equivalent (mSv/MBq)	1.5E+01	2.4E+01	3.6E+01	7.8E+01	1.4E+02

Thyroid uptake 55%

Absorbed dose per unit activity administered (mGy/MBq)					
Organ	Adult	15 year	10 year	5 year	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 equivalent (mSv/MBq)	2.4E+01	3.7E+01	5.6E+01	1.2E+02	2.2E+02

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate, sodium bicarbonate, sodium thiosulfate, sodium hydroxide and water for injections.

6.2 Incompatibility

None known to date.

6.3 Shelf life

The expiry date for this product is 29 days from the day of manufacture.

6.4 Storage precaution

The finished product should be stored at a temperature ranging between +15 °C and +25 °C.

Storage should be in accordance with national regulations for radioactive materials.

6.5 Nature and Contents of Container

15 mL colourless, European Pharmacopoeia type I, drawn glass vial, closed with a grey rubber stopper and an aluminium capsule.

6.6 Instructions for Use/handling

Usual precautions regarding sterility and radioprotection should be respected.

Before use, packaging, pH, radioactivity and gamma spectrum will be checked.

The vial should never be opened and must be kept inside its lead shielding.

The product should be aseptically withdrawn through the stopper using sterilized single use needle and syringe after disinfection of the stopper.

Solutions of sodium iodide ¹³¹I should be handled strictly under a ventilated hood and the personnel handling these solutions should be given a urinary radiotoxicologic control examination.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

Radioactive waste must be disposed of in conformity with the relevant national and international regulations.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL/11876/0014.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

19 September 1997

10. DATE OF REVISION OF THE TEXT

12/2008