SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Iodide (I-123) Injection Curiumpharma

(Curiumpharma catalogue number: DRN 5375)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active ingredient

Sodium Iodide (I-123), 37 MBq/ml at activity reference date and hour.

2.2 Physical characteristics

Iodine-123 is a cyclotron product with a physical half-life of 13.21 h.

Iodine-123 decays emitting pure gamma radiation with predominant energies of 159 keV and 27 keV.

^{123}I is obtained by proton irradiation of enriched Xenon. The radionuclidic purity of the product at expiry date and time is: ^{123}I > 99.9%. The only detectable radionuclidic impurities are ^{121}Te ≤ 900 Bq/MBq and ^{125}I ≤ 1500 Bq/MBq at expiry date and time.

3 PHARMACEUTICAL FORM

Solution for injections. ATC code: V10X A01

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium iodide (I-123) is used as a diagnostic agent in the functional or morphological study of the thyroid gland by means of:

- Scintigraphy
- Radioactive iodine uptake test

The 24 hours uptake data are generally used in calculating the therapeutic dose.

4.2 Posology and method of administration

The recommended activities for an adult patient (70 kg) lies between 3.7 to 14.8 MBq. The lower activity (3.7 MBq) is recommended for uptake studies and the higher doses (11.1 - 14.8 MBq) for thyroid scintigraphy. However, for each individual case, the dose prescribed must be determined by the attending specialist.
Determination of the rate of thyroid iodine-123 uptake should be carried out in accordance with well established standard procedures. The activity dosages for children may be calculated from the recommended range of adult dosages, adjusted according to the following equation:

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

In very young children the maximal adult dosage of 14.8 MBq should be used in the equation in order to obtain images of sufficient quality.

^{123}I must be given as an intravenous injection: as a routine check, the activity in the syringe should be measured immediately prior to administration. Imaging is performed 3 - 6 hours after administration.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

This radiopharmaceutical may be used and administered only by authorised persons.

Radiopharmaceuticals intended for administration to patients should be prepared by the user in a manner which satisfies both cardiological safety and pharmaceutical quality requirements. Particular care should be taken when administering radiopharmaceuticals to young persons, women of childbearing age and mothers who are breast-feeding.

4.5 Interaction with other medicinal products and other forms of interactions

Many drugs will modify the uptake of iodine by the thyroid gland. These drugs are listed in the table. The time necessary for % uptake to return to baseline after cessation of each group of drugs is given.

DRUGS AFFECTING THYROID UPTAKE

Type of medication	**Time after withdrawal drug for thyroid uptake to return to**

	baseline.
Amiodarone	4 weeks
Antithyroid (propylthiouracil, methimazol)	1 week
Lithium	4 weeks
Natural or synthetic thyroid preparations (thyroxine sodium, liothyronine sodium thyroid)	2 - 3 weeks
Expectorants, vitamins	2 weeks
Perchlorate	1 week
Phenylbutazone	1 - 2 weeks
Salicylates	1 week
Steroids	1 week
Sodium nitroprusside	1 week
Sulfobromophtalein sodium	1 week
Miscellaneous agents: Anticoagulants Antihistamines Antiparasitics Penicillins Sulfonamides Tolbutamide Thiopental	1 week
Benzodiazepines	4 weeks
Topical iodides	1 - 9 months
Intravenous contrast agents	1 - 2 months
Oral cholecystographic agents	6 - 9 months
Oil-based iodinated contrast agents:	
Bronchographic	6 - 12 months
Myelographic	2 - 10 years

4.6 Fertility, pregnancy and lactation

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.
Radionuclide procedures carried out on pregnant women also involve radiation doses to the fetus. Only imperative investigations should be carried out during pregnancy, when the likely benefit exceeds the risk incurred by mother and fetus.
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 secretory activity in breast milk. If the administration is found necessary the breast-feeding should be interrupted for 1.5-3 days following the administration of I-123 that contains I-125 and/or I-124 as radio contaminant. Breast-feeding can be restarted when the level in milk will not result in a radiation dose to the child greater than 1 mSv.

4.7 Effects on ability to drive and to use machines

Effects on the ability to drive or to operate machinery have not been described.

4.8 Undesirable effects

For each patient, exposure to ionising radiation must be justifiable on the basis of likely clinical 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. 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 effects will occur with negligible frequency because of the low radiation dose incurred.
For most diagnostic investigations using a nuclear medicine procedure the radiation dose delivered (EDE) is less than 20 mSv. Higher doses may be justified in some clinical circumstances. Isolated cases of allergic reactions have been reported without more precise information about the frequency and the details of the type of phenomena.

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 at Statens legemiddelverk.
Website: www.legemiddelverket.no/meldeskjema

4.9 Overdose

In the event of the administration of an overdose of a radiopharmaceutical, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body. In the event of an overdose of Sodium Iodide I-123, the use of a blocking agent such as potassium perchlorate to minimize irradiation to the thyroid, and diuresis and frequent voiding of urine is recommended. Care should be taken to avoid contamination from radioactivity eliminated by the patient using such methods.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

At doses used in diagnostic investigations, sodium iodide has not been observed to exert any pharmacodynamic effects.

5.2 Pharmacokinetic properties

Intravenously administered iodide is taken by the thyroid - about 20 % of the available radioactivity enters the thyroid in one pass of the blood volume. Normal thyroid clearance of blood iodide is 20 - 50 ml/min with an increase to 100 ml/min in thyroid deficiency. Peak levels of iodide occur in thyroid gland within a few hours so that diagnostic imaging can take place from one hours after dosing.
The half-time of iodide elimination from the thyroid is estimated at 80 days so that the physical half-life of I-123 governs the temporal opportunity for imaging.
Without considering the thyroid uptake, the iodide leaves the body stream mainly by

urinary excretion (37 - 75 %), while faecal excretion is low (about 1 %).

5.3 Preclinical safety data

Known toxic effects of relatively very high dose of sodium iodide are not relevant to this use of I-123 to image the thyroid for diagnostic purposes.

No data are available from animal models about toxicity with repeated dose administration and about reproduction toxicity.

Sodium iodide I-123 was not investigated for mutagenicity and carcinogenic/oncogenic potential.

5.4 Radiation dosimetry

As a consequence of the production procedure of I-123, I-125 is present as an impurity. This increases the radiation dose delivered.

Also the production procedure leads to the formation of Te-121. This impurity also must be taken into consideration as source of radiation to the patient.

The ICRP model used for the dosimetry calculations relates to intravenous administrations.
For the maximum recommended dose of 14.8 MBq ^{123}I the EDE in patients with 35% thyroid uptake is calculated as 2.2 mSv.
Radiation dosimetry for respectively I-123 and I-125 is reported in ICRP publication 53 n° (1987) and is as follows:

^{123}I 13.2 hours

Thyroid blocked, uptake 0 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	7.0E-03	8.7E-03	1.4E-02	2.1E-02	3.9E-02
*Bladder wall	9.0E-02	1.1E-01	1.6E-01	2.4E-01	4.5E-01
Bone surfaces	8.1E-03	9.7E-03	1.5E-02	2.4E-02	4.6E-02
Breast	5.6E-03	5.6E-03	8.1E-03	1.3E-02	2.5E-02
GI-Tract					
Stomach wall	6.9E-03	8.5E-03	1.4E-02	2.1E-02	3.7E-02
*Small intest	8.5E-03	1.0E-02	1.6E-02	2.5E-02	4.6E-02
*ULI wall	8.0E-03	9.9E-03	1.5E-02	2.4E-02	4.3E-02
*LLI wall	9.7E-03	1.2E-02	1.9E-02	2.9E-02	5.4E-02
Kidneys	1.1E-02	1.4E-02	2.0E-02	2.9E-02	5.1E-02
Liver	6.7E-03	8.2E-03	1.3E-02	2.0E-02	3.7E-02
Lungs	6.1E-03	7.8E-03	1.2E-02	1.9E-02	3.5E-02
Ovaries	9.8E-03	1.2E-02	1.9E-02	3.0E-02	5.3E-02
Pancreas	7.6E-03	9.1E-03	1.4E-02	2.2E-02	4.1E-02
Red marrow	9.4E-03	1.1E-02	1.7E-02	2.6E-02	4.7E-02
Spleen	7.0E-03	8.3E-03	1.3E-02	2.0E-02	3.7E-02
Testes	6.9E-03	9.4E-03	1.5E-02	2.5E-02	4.8E-02
Thyroid	5.1E-03	7.7E-03	1.2E-02	2.0E-02	3.7E-02
Uterus	1.4E-02	1.7E-02	2.8E-02	4.3E-02	7.6E-02
Other tissue	6.4E-03	7.7E-03	1.2E-02	1.9E-02	3.5E-02
Effective					

dose equivalent (mSv/MBq)	**1.3E-02**	**1.6E-02**	**2.4E-02**	**3.7E-02**	**6.7E-02**

Incomplete blockage:

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

	Adult	**15 years**	**10 years**	**5 years**	**1 year**
Uptake: 0.5 %	1.6E-02	2.0E-02	3.1E-02	5.2E-02	9.6E-02
Uptake: 1 %	1.9E-02	2.5E-02	3.8E-02	6.7E-02	1.3E-01
Uptake: 2 %	2.5E-02	3.4E-02	5.2E-02	9.9E-02	1.8E-01

Thyroid blocked, uptake 15 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	6.3E-03	8.3E-03	1.3E-02	2.0E-02	3.7E-02
*Bladder wall	7.6E-02	9.5E-02	1.4E-01	2.1E-01	3.8E-01
Bone surfaces	7.1E-03	9.1E-03	1.4E-02	2.2E-02	4.1E-02
Breast	4.7E-03	4.7E-03	7.3E-03	1.2E-02	2.3E-02
GI-Tract					
Stomach wall	6.8E-02	8.5E-02	1.2E-01	2.0E-01	3.8E-01
*Small intest	4.3E-02	5.4E-02	9.1E-02	1.4E-01	2.7E-01
*ULI wall	1.8E-02	1.9E-02	2.9E-02	4.5E-02	7.7E-02
*LLI wall	1.1E-02	1.4E-02	2.2E-02	3.3E-02	6.0E-02
Kidneys	1.0E-02	1.3E-02	1.8E-02	2.7E-02	4.6E-02
Liver	6.2E-03	7.6E-03	1.3E-02	2.1E-02	3.8E-02
Lungs	5.7E-03	7.2E-03	1.1E-02	1.8E-02	3.4E-02
Ovaries	1.2E-02	1.6E-02	2.5E-02	3.8E-02	6.8E-02
Pancreas	1.4E-02	1.6E-02	2.4E-02	3.5E-02	6.1E-02
Red marrow	9.4E-03	1.2E-02	1.7E-02	2.5E-02	4.3E-02
Spleen	9.5E-03	1.1E-02	1.7E-02	2.5E-02	4.4E-02
Testes	5.3E-03	7.2E-03	1.2E-02	2.0E-02	3.8E-02
Thyroid	1.9E+00	3.0E+00	4.5E+00	9.8E+00	1.9E+01
Uterus	1.5E-02	1.9E-02	3.1E-02	4.9E-02	8.6E-02
Other tissue	6.8E-03	8.5E-03	1.3E-02	2.1E-02	3.9E-02
Effective dose equivalent (mSv/MBq)	**7.5E-02**	**1.1E-01**	**1.7E-01**	**3.5E-01**	**6.5E-01**

Thyroid blocked, uptake 35 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	6.5E-03	8.4E-03	1.3E-02	2.1E-02	3.8E-02
*Bladder wall	6.0E-02	7.4E-02	1.1E-01	1.6E-01	3.0E-01
Bone surfaces	7.9E-03	1.1E-02	1.6E-02	2.5E-02	4.6E-02
Breast	5.2E-03	5.2E-03	8.5E-03	1.5E-02	2.7E-02
GI-Tract					
Stomach wall	6.8E-02	8.5E-02	1.2E-01	2.0E-01	3.8E-01
*Small intest	4.2E-02	5.4E-02	9.0E-02	1.4E-01	2.7E-01
*ULI wall	1.8E-02	1.9E-02	2.9E-02	4.5E-02	7.6E-02
*LLI wall	1.0E-02	1.4E-02	2.1E-02	3.2E-02	5.8E-02
Kidneys	9.1E-03	1.1E-02	1.6E-02	2.4E-02	4.1E-02
Liver	6.3E-03	7.8E-03	1.3E-02	2.1E-02	4.0E-02
Lungs	6.5E-03	8.6E-03	1.4E-02	2.2E-02	4.2E-02
Ovaries	1.1E-02	1.5E-02	2.4E-02	3.7E-02	6.6E-02
Pancreas	1.4E-02	1.6E-02	2.4E-02	3.6E-02	6.2E-02
Red marrow	1.0E-02	1.3E-02	1.9E-02	2.8E-02	4.8E-02
Spleen	9.6E-03	1.1E-02	1.7E-02	2.5E-02	4.5E-02
Testes	5.0E-03	6.8E-03	1.1E-02	1.8E-02	3.5E-02
Thyroid	4.5E+00	7.0E+00	1.1E+01	2.3E+01	4.3E+01
Uterus	1.4E-02	1.7E-02	2.9E-02	4.4E-02	7.9E-02
Other tissue	8.0E-03	1.0E-02	1.6E-02	2.6E-02	4.9E-02
Effective dose equivalent (mSv/MBq)	**1.5E-01**	**2.3E-01**	**3.5E-01**	**7.4E-01**	**1.4E+00**

Thyroid blocked, uptake 55 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	6.5E-03	8.5E-03	1.4E-02	2.1E-02	3.9E-02
*Bladder wall	4.3E-02	5.3E-02	7.9E-02	1.2E-01	2.2E-01
Bone surfaces	8.6E-03	1.2E-02	1.8E-02	2.8E-02	5.1E-02
Breast	5.6E-03	5.6E-03	9.5E-03	1.7E-02	3.1E-02
GI-Tract					
Stomach wall	6.8E-02	8.5E-02	1.2E-01	2.0E-01	3.9E-01
*Small intest	4.2E-02	5.4E-02	9.1E-02	1.4E-01	2.7E-01
*ULI wall	1.8E-02	1.9E-02	2.9E-02	4.4E-02	7.6E-02
*LLI wall	9.8E-03	1.3E-02	2.0E-02	3.0E-02	5.5E-02
Kidneys	9.1E-03	1.1E-02	1.6E-02	2.4E-02	4.1E-02
Liver	6.4E-03	7.9E-03	1.3E-02	2.2E-02	4.1E-02
Lungs	7.2E-03	9.7E-03	1.6E-02	2.6E-02	4.8E-02
Ovaries	1.1E-02	1.5E-02	2.3E-02	3.6E-02	6.4E-02
Pancreas	1.4E-02	1.6E-02	2.5E-02	3.6E-02	6.3E-02
Red marrow	1.1E-02	1.5E-02	2.1E-02	3.0E-02	5.2E-02
Spleen	9.7E-03	1.1E-02	1.7E-02	2.6E-02	4.6E-02
Testes	4.6E-03	6.2E-03	1.0E-02	1.6E-02	3.2E-02
Thyroid	7.0E+00	1.1E+01	1.7E+01	3.6E+01	6.8E+01
Uterus	1.2E-02	1.6E-02	2.6E-02	4.0E-02	7.2E-02
Other tissue	9.2E-03	1.2E-02	1.9E-02	3.1E-02	5.8E-02
Effective dose equivalent (mSv/MBq)	**2.3E-01**	**3.5E-01**	**5.3E-01**	**1.1E+00**	**2.1E+00**

^{125}I 60.14 days

Thyroid blocked, uptake 0 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	4.8E-03	6.6E-03	1.1E-02	1.9E-02	3.7E-02
*Bladder wall	1.0E-01	1.3E-01	1.9E-01	2.9E-01	5.4E-01
Bone surfaces	7.4E-03	9.3E-03	1.6E-02	2.7E-02	5.7E-02
Breast	5.1E-03	5.1E-03	7.4E-03	1.2E-02	2.4E-02
GI-Tract					
Stomach wall	5.3E-03	6.5E-03	1.0E-02	1.8E-02	3.5E-02
*Small intest	5.8E-03	6.8E-03	1.2E-02	2.0E-02	4.1E-02
*ULI wall	5.8E-03	6.8E-03	1.2E-02	1.9E-02	3.9E-02
*LLI wall	6.7E-03	8.1E-03	1.3E-02	2.3E-02	4.8E-02
Kidneys	1.0E-02	1.3E-02	1.9E-02	2.8E-02	5.1E-02
Liver	5.4E-03	6.4E-03	1.1E-02	1.8E-02	3.5E-02
Lungs	5.5E-03	6.9E-03	1.1E-02	1.9E-02	3.7E-02
Ovaries	6.4E-03	7.8E-03	1.4E-02	2.4E-02	4.8E-02
Pancreas	5.6E-03	6.7E-03	1.1E-02	1.9E-02	3.7E-02
Red marrow	8.3E-03	1.0E-02	1.7E-02	2.9E-02	5.9E-02
Spleen	5.6E-03	6.5E-03	1.1E-02	1.8E-02	3.6E-02
Testes	5.0E-03	6.5E-03	1.2E-02	2.1E-02	4.4E-02
Thyroid	4.7E-03	6.3E-03	1.1E-02	1.8E-02	3.6E-02
Uterus	9.5E-03	1.2E-02	2.2E-02	3.8E-02	7.5E-02
Other tissue	5.2E-03	6.3E-03	1.0E-02	1.7E-02	3.4E-02
Effective dose equivalent (mSv/MBq)	**1.2E-02**	**1.5E-02**	**2.3E-02**	**3.7E-02**	**7.3E-02**

Incomplete blockage:

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

	Adult	15 years	10 years	5 years	1 year
Uptake: 0.5 %	1.5E-01	2.4E-01	3.6E-01	7.7E-01	1.4E+00
Uptake: 1 %	3.0E-01	4.6E-01	6.9E-01	1.5E+00	2.8E+00
Uptake: 2 %	5.8E-01	9.0E-01	1.4E+00	3.0E+00	5.6E+00

Thyroid blocked, uptake 15 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	3.6E-03	5.1E-03	8.9E-03	1.5E-02	3.3E-02
*Bladder wall	8.5E-02	1.1E-01	1.6E-01	2.4E-01	4.6E-01
Bone surfaces	1.6E-02	4.1E-02	5.3E-02	8.0E-02	1.4E-01
Breast	4.6E-03	4.5E-03	8.5E-03	1.9E-02	5.1E-02
GI-Tract					
Stomach wall	7.1E-02	9.0E-02	1.3E-01	2.2E-01	4.4E-01
*Small intest	4.2E-02	5.5E-02	9.5E-02	1.6E-01	3.0E-01
*ULI wall	1.6E-02	1.4E-02	2.4E-02	3.9E-02	7.6E-02
*LLI wall	7.5E-03	9.5E-03	1.6E-02	2.7E-02	5.4E-02
Kidneys	8.6E-03	1.1E-02	1.6E-02	2.4E-02	4.6E-02
Liver	4.2E-03	4.9E-03	9.4E-03	1.7E-02	3.8E-02
Lungs	8.7E-03	1.3E-02	3.1E-02	6.2E-02	1.3E-01
Ovaries	6.9E-03	9.8E-03	1.8E-02	3.1E-02	6.2E-02
Pancreas	9.2E-03	1.0E-02	1.8E-02	2.9E-02	5.7E-02
Red marrow	1.7E-02	3.9E-02	5.1E-02	7.7E-02	1.4E-01
Spleen	5.8E-03	6.6E-03	1.2E-02	1.9E-02	4.3E-02
Testes	3.6E-03	4.7E-03	8.8E-03	1.6E-02	3.4E-02
Thyroid	1.4E+02	2.0E+02	2.6E+02	5.1E+02	7.9E+02
Uterus	9.2E-03	1.2E-02	2.4E-02	4.1E-02	8.2E-02
Other tissue	5.3E-02	7.0E-02	1.1E-01	1.7E-01	2.9E-01
Effective dose equivalent (mSv/MBq)	**4.3E+00**	**6.0E+00**	**8.0E+00**	**1.5E+01**	**2.4E+01**

Thyroid blocked, uptake 35 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	3.5E-03	5.0E-03	8.9E-03	1.6E-02	3.7E-02
*Bladder wall	6.6E-02	8.3E-02	1.2E-01	1.9E-01	3.6E-01
Bone surfaces	3.1E-02	8.6E-02	1.1E-01	1.6E-01	2.7E-01
Breast	5.9E-03	5.7E-03	1.3E-02	3.2E-02	9.5E-02
GI-Tract					
Stomach wall	7.1E-02	9.0E-02	1.3E-01	2.2E-01	4.4E-01
*Small intest	4.2E-02	5.5E-02	9.5E-02	1.6E-01	3.0E-01
*ULI wall	1.6E-02	1.4E-02	2.4E-02	3.9E-02	7.5E-02
*LLI wall	7.2E-03	9.1E-03	1.5E-02	2.6E-02	5.1E-02
Kidneys	7.6E-03	9.3E-03	1.4E-02	2.2E-02	4.4E-02
Liver	4.2E-03	5.0E-03	1.0E-02	1.9E-02	4.5E-02
Lungs	1.5E-02	2.3E-02	6.1E-02	1.2E-01	2.8E-01
Ovaries	6.7E-03	9.6E-03	1.7E-02	3.0E-02	6.0E-02
Pancreas	9.2E-03	1.0E-02	1.8E-02	2.9E-02	6.1E-02
Red marrow	3.0E-02	7.9E-02	9.9E-02	1.5E-01	2.7E-01
Spleen	5.8E-03	6.6E-03	1.2E-02	2.0E-02	5.1E-02
Testes	3.5E-03	4.5E-03	8.2E-03	1.5E-02	3.1E-02
Thyroid	3.3E+02	4.7E+02	6.2E+02	1.2E+03	1.9E+03
Uterus	8.3E-03	1.1E-02	2.1E-02	3.7E-02	7.4E-02
Other tissue	1.2E-01	1.6E-01	2.4E-01	3.8E-01	6.4E-01
Effective dose equivalent (mSv/MBq)	**9.9E+00**	**1.4E+01**	**1.9E+01**	**3.6E+01**	**5.6E+01**

Thyroid blocked, uptake 55 %
Absorbed Dose
per unit activity administered (mGy/MBq)

Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	3.6E-03	5.1E-03	9.2E-03	1.7E-02	4.1E-02
*Bladder wall	4.7E-02	5.8E-02	8.8E-02	1.3E-01	2.5E-01
Bone surfaces	4.5E-02	1.3E-01	1.6E-01	2.4E-01	4.0E-01
Breast	7.3E-03	7.0E-03	1.7E-02	4.6E-02	1.4E-01
GI-Tract					
Stomach wall	7.1E-02	9.0E-02	1.3E-01	2.2E-01	4.5E-01
*Small intest	4.2E-02	5.5E-02	9.5E-02	1.5E-01	3.0E-01
*ULI wall	1.6E-02	1.4E-02	2.4E-02	3.9E-02	7.5E-02
*LLI wall	7.0E-03	8.8E-03	1.5E-02	2.4E-02	4.9E-02
Kidneys	6.4E-03	7.9E-03	1.2E-02	1.9E-02	4.3E-02
Liver	4.2E-03	5.1E-03	1.1E-02	2.2E-02	5.2E-02
Lungs	2.1E-02	3.4E-02	9.1E-02	1.9E-01	4.2E-01
Ovaries	6.6E-03	9.4E-03	1.7E-02	2.9E-02	5.8E-02
Pancreas	9.2E-03	1.0E-02	1.8E-02	3.0E-02	6.6E-02
Red marrow	4.3E-02	1.2E-01	1.5E-01	2.2E-01	4.0E-01
Spleen	5.8E-03	6.6E-03	1.2E-02	2.0E-02	5.9E-02
Testes	3.4E-03	4.4E-03	7.7E-03	1.4E-02	2.8E-02
Thyroid	5.2E+02	7.4E+02	9.7E+02	1.9E+03	2.9E+03
Uterus	7.5E-03	1.0E-02	1.9E-02	3.3E-02	6.7E-02
Other tissue	1.8E-01	2.4E-01	3.8E-01	5.9E-01	9.9E-01
Effective dose equivalent (mSv/MBq)	**1.6E+01**	**2.2E+01**	**2.9E+01**	**5.6E+01**	**8.8E+01**

^{121}Te 16.8 days

The radiation dose from ^{121}Te, homogeneously distributed throughout the whole body is 4.6E-02 mSv/MBq. The calculated effective dose equivalent is 4.6E-02 mSv/MBq.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium chloride, sodium hydrogencarbonate, water for injections.

6.2 Incompatibilities
None known.

6.3 Shelf life
The expiry date for this product is 20 hours from activity reference date/time as stated on the label.

6.4 Special precautions for storage
Do not store the preparation above 25°C. However if multi-dose use is intended, each aliquot should be removed under aseptic conditions and then the vial should be stored

at 2°C-8°C after removal of the first aliquot and for no longer than 24 hours or up to end of shelf life, whichever comes first.

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

6.5 Nature and contents of container

Sodium Iodide (I123) injection is supplied in a glass bottle (Type I Ph.Eur.) closed with a bromobutyl rubber stopper sealed with an aluminium crimp cap. Each bottle is enclosed in a lead container of appropriate thickness.

Available pack size: 37, 74, 185 and 370 MBq.

6.6 Special precautions for disposal and other handling

The sodium iodide (I-123) solution is ready for use. Adequate precautions must be taken to prevent contamination concerning the radioactivity eliminated by the patients. All residue must be considered as radioactive waste and must be disposed in accordance with the relevant national regulations.

7 MARKETING AUTHORISATION HOLDER

Curium Netherlands B.V.
Westerduinweg 3
1755 LE PETTEN
Holland
Tel.: +31 224 567890
Fax.: +31 224 567008

8 MARKETING AUTHORISATION NUMBER

MT 8356

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 May 2005/10 May 2012

10 DATE OF REVISION OF THE TEXT

26.09.2019