SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Iodide (I-123) Injection

(Curium Netherlands catalogue number: DRN 5375)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient

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

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.

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

3 PHARMACEUTICAL FORM

Solution for injections.

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:

Paediatric dosage (MBq)= Adult dosage (MBq) x 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.

1

¹²³I 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

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 diagnostic information.

Paediatric population

Paediatric population, see section 4.2.

General warnings:

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

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Specific warnings

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium – free".

4.5 Interaction with other medicinal products and other forms of interaction

The uptake of ¹²³I-iodide may be decreased by recent administration of iodinated contrast materials, by intake of stabile iodine in any form, or by thyroid, antithyroid, and certain other drugs. Accordingly, the patient should be questioned carefully regarding diet, previous medication, and procedures involving radiographic contrast media. Relevant medication including the ones mentioned below should be withheld prior to the administration of sodium¹²³I-iodide

Active substances: Withdrawal period to administration of sodium 123I-iodide

Antithyroid agents (e.g.) carbimazole, methimazole, propyluracil), perchlorate: 1 week.

Salicylates, steroids, sodium nitroprusside, sodium sulfobromophthalein, anticoagulants,

antihistamines, antiparasitics, penicillins, sulfonamides, tolbutamide, thiopental: 1 week.

Phenylbutazone: 1-2 weeks.

Expectorants and vitamins: 2 weeks.

Natural or synthetic thyroid preparations (levothyroxine sodium, liothyronine sodium: 2-3 weeks.

Amiodarone, benzodiazepines, lithium: approx. 4 weeks.

Iodine-containing preparations for topical use: 1-9 months.

Intravenous contrast agents: 1-2 months.

Iodine containing contrast agent: up to 1 year.

4.6 Fertility, pregnancy and lactation

Woman of childbearing potential

When it is necessary to administer a 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. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques using ionising radiation should offered to the patient.

Pregnancy

Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only imperative investigations should be carried out during pregnancy, when the likely benefit exceeds the risk incurred by the mother and foetus.

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 to what is the most appropriate choice of radiopharmaceutical, bearing in mind the secretion 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. Expressed milk should be discarded.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The frequencies of undesirable effects are defined as follows:

Very common ($\geq 1/10$), common ($\geq 1/100$ to <1/10), uncommon ($\geq 1/1,000$ to <1/100), rare ($\geq 1/10,000$ to <1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

Immune system disorders

Not known: hypersensitivity

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 2.2 mSv when the maximal recommended activity of 14.8 MBq is administered, these adverse effects are expected to occur with a low probability.

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: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

In the event of the administration of an overdose of Iodine I-123, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by diuresis and frequent voiding of urine. A blocking agent such as potassium perchlorate should be used to minimise irradiation to the thyroid.

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 hour 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 blood stream chiefly by urinary excretion (37 - 75 %), while faecal excretion is low (about 1 %).

5.3 Pre-clinical 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.

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 time for this product is 20 hours after the activity reference date/time as stated on the label.

6.4 Special Precautions for Storage

The preparation should be stored at 15 - 25 °C (room temperature).

However, if multi-dose use is intended, each aliquot should be removed under aseptic conditions and then the vial should be stored at 2 - 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 Content of Container

Sodium Iodide (I123) injection is supplied in a glass bottle (Type I Ph.Eur.) closed with a 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

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 Netherlands

8 MARKETING AUTHORISATION NUMBER

PL 12288/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/10/2002

10 DATE OF REVISION OF THE TEXT

30/06/2023

11 DOSIMETRY

As a consequence of the production procedure of I-123, I-125 is present as 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:

¹²³I 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 equiv	alent				
(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	2.02 02	2.02 03	J.52 03	1.72 02	3.1 2 0 2
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

12

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.