



27. February 2020

SUMMARY OF PRODUCT CHARACTERISTICS

for

Sodium iodide (I123) injection, solution for injection

1 NAME OF THE MEDICINAL PRODUCT

Sodium iodide (I123) injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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: $^{123}\text{I} > 99.9\%$. The only detectable radionuclidic impurities are $^{121}\text{Te} \leq 900 \text{ Bq/MBq}$ and $^{125}\text{I} \leq 1500 \text{ Bq/MBq}$ at expiry date and time.

Excipients: Sodium

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

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 activity 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.

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.

The instructions for preparation of radiopharmaceuticals are given in section 12.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and special precautions for use

Particular care should be taken when administering radiopharmaceuticals to young persons, women of child bearing age and mothers who are breast feeding.

This medicinal product contains:

Sodium: 3.54 mg/ml

This needs to be taken into consideration for patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Many drugs will modify the uptake of iodine by the thyroid gland. These drugs are listed in table 1. The time necessary for the uptake to return to baseline after cessation of each group of drugs is given.

Table 1. Effect of several drugs on the uptake of iodine by the thyroid gland.

Type of medication	Time after withdrawal of drug for thyroid uptake to return to baseline
Amiodarone	4 weeks
Antithyroid (propylthiouracil, thiamazole)	1 week
Lithium	4 weeks
Natural or synthetic thyroid preparations (levothyroxine 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
Sulfobromophthalein 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 **Pregnancy and lactation**

Pregnancy

Only imperative investigations should be carried out during pregnancy, when the likely benefit exceeds the risk incurred by mother and foetus.

Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus.

When it is necessary to administer radioactive medicinal product to women of child-bearing 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 exist 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.

Lactation

If the administration is found necessary the breast-feeding should be interrupted for 1.5 - 3 days following the administration of iodine-123 that contains iodine-125 and/or iodine-124 as radio contaminant. Expressed milk should be discarded. Breast-feeding can be restarted when the level in milk will not result in a radiation dose to the child greater than 1 mSv.

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.

4.7 **Effects on the 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**

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 reasonable 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 effective dose 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

Lægemiddelstyrelsen

Axel Heides Gade 1

DK-2300 København S

Websted: www.meldenbivirkning.dk

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) Injection, a blocking agent such as potassium perchlorate should be used to minimise irradiation to the thyroid. In addition, 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

V 09 FX 02 - Diagnostic radiopharmaceuticals, thyroid, sodium Iodide (I-123).

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 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.

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.

6.1 Storage 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 the 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.

Not all pack sizes may be marketed

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 residues must be considered as radioactive waste and must be disposed of in accordance with the relevant national regulations.

This radiopharmaceutical may be used and administered only by authorised persons. Any unused product or waste material should be disposed of in accordance with local requirements for radioactive material.

7 MARKETING AUTHORISATION HOLDER

Curium Netherlands B.V.
Westerduinweg 3
1755 LE PETTEN
Holland

8 MARKETING AUTHORISATION NUMBER

DK R 1122

9 DATE OF FIRST AUTHORISATION

31 January 1995

10 DATE OF REVISION OF THE TEXT

27. February 2020

11. DOSIMETRY

As 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 ¹²³I 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
*ULI 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
*ULI 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
*ULI 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
*ULI 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

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.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Radiopharmaceuticals intended for administration to patients should be prepared by the user in a manner which satisfies both radiological 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.