SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium Iodide [^{123}I] injection, GE Healthcare

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Iodide [^{123}I], 37 MBq/ml at reference date and hour.
At calibration time, the radionuclidic purity is at least 99.9 % and the main radionuclidic impurities (iodine-125 and tellurium-121) occur for less than 0.05 %.
Iodine-123 is a cyclotron product with a physical half-life of 13.2 hours. Iodine-123 decays emitting pure gamma radiation with predominant energies of 159 keV and 27 keV.

Excipient(s) with known effect:
This medicinal product contains:Sodium 3.99 mg/ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Sodium Iodide [^{123}I] Injection 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

Posology

Adults
The recommended activities for an adult patient (70 kg) is between 3.7 and 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 is decided by the specialist concerned.

Determination of the rate of thyroid iodine-123 uptake should be carried out in accordance with well established standard procedures.

Paediatric population

The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and to adolescents may be calculated
according to the EANM Dosage Card (Version 5.7.2016) for a given patient weight as tabulated below. National diagnostic reference levels should not be exceeded.

Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)	Weight (kg)	Activity (MBq)
3	3.0	22	5.6	42	11.4
4	3.0	24	6.0	44	12.0
6	3.0	26	6.6	46	12.6
8	3.0	28	7.2	48	13.2
10	3.0	30	7.8	50	13.8
12	3.0	32	8.4	52-54	14.8
14	3.4	34	9.0	56-28	14.8
16	3.8	36	9.6	60-62	14.8
18	4.4	38	10.2	64-66	14.8
20	5.0	40	10.8	68	14.8

Sodium Iodide [^{123}I] Injection must be given as an intravenously injection; as a routine check, the activity in the injection should be measured immediately prior to administration. Imaging is done 3-6 hours after administration.

Renal impairment / Hepatic impairment

Sodium Iodide has not been studied in patients with significant renal or hepatic impairment. Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Method of administration
For instructions on preparation of the medicinal product before administration, see section 12.

For patient preparation, see section 4.4.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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.

Potential for hypersensitivity or anaphylactic reactions
If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product

must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies the necessary medicinal products and equipment such as endotracheal tube and ventilator must be readily available.

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.

Renal impairment / Hepatic impairment
Sodium Iodide has not been studied in patients with significant renal or hepatic impairment. Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

Paediatric population:
For information on the use in paediatric population, see section 4.2. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11).

Patient preparation
The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.

After the procedure
Close contact with infants and pregnant women should be restricted during 48 hours after the administration.

Specific warnings
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.

Precautions with respect to environmental hazard see section 6.6.

4.5 Interactions with other medicinal products and other forms of interaction

The uptake of sodium iodide [^{123}I] may be decreased by recent administration of iodinated contrast materials, by intake of stable 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 sodium iodide[^{123}I] (Table 1).

Table 1

Active substance	**Withdrawal period prior to administration of Sodium Iodide [^{123}I]**
Amiodarone	4 weeks
Antithyroid agents (e.g. carbimazole, 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
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
Iodide containing contrast agent	Up to 1 year

Paediatric population
Interaction studies have only been performed in adults.

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.

Pregnancy:
Radionuclide procedures carried out on pregnant women also involve radiation dose to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.

Breast-feeding:
Before administering radiopharmaceuticals to a mother who is breast-feeding consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast-feeding, and as to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary 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 feeds 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.

Fertility
No studies on fertility have been performed.

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 (≥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 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 reactions are expected to occur with a low probability. 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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:

Norge
Statens legemiddelverk
Nettside: www.legemiddelverket.no/meldeskjema

4.9 Overdose
In the event of the administration of an overdose of Sodium Iodide [^{123}I] injection, the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. A blocking agent such as potassium perchlorate should be used to minimise irradiation to the thyroid.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: various thyroid diagnostic radiopharmaceuticals
ATC code: V09FX02.

Pharmacodynamic effects
At the chemical concentrations used for diagnostic examinations, Sodium Iodide does not appear to have any pharmacodynamic activity.

5.2 Pharmacokinetic properties
Distribution
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.

Organ Uptake
Peak levels of iodide occur in thyroid gland within a few hours so that diagnostic imaging can take place from one hour after dosing.

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

Renal/Hepatic impairment
The pharmacokinetics in patients with renal or hepatic impairment has not been characterised.

5.3 Preclinical safety data

Known toxic effects of relatively very high doses 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 [123-I] injection has not been investigated for mutagenicity and carcinogenic/oncogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid
Sodium hydroxide
Sodium thiosulfate
Sodium bicarbonate
Sodium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

Can be used up to 36 hours post calibration time indicated on the label.
Once opened store in a refrigerator (2°C-8°C) and use within one working day.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.
Store either in the original lead container or in equivalent shielding.
Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

10 ml medicinal glass vial, closed with a Teflon coated rubber stopper and sealed with an aluminium cap. Each vial is enclosed in a lead container of appropriate thickness.

Pack size: 18.5 to 370 MBq (one 10 ml vial)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

General warning
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. Appropriate aseptic precautions should be taken.

If at any time in the preparation of this product the integrity of this container is compromised it should not be used.

Administration procedures should be carried out in a way to minimize risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

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

GE Healthcare B.V.
De Rondom 8
5612 AP Eindhoven
The Netherlands

8. MARKETING AUTHORISATION NUMBER

MT nr: 94-193

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

2005-05-31/2010-05-31

10. DATE OF (PARTIAL) REVISION OF THE TEXT

24.05.2017

11. DOSIMETRY

Depending on the production procedure of iodine-123, impurities like iodine-125 and/or iodine-124 may be present as longer life contaminants increasing the radiation dosimetry to the different organs. The ICRP model refers to intravenous administration. At reference time, the radionuclidic purity is at least 99.9 % and the main radionuclide impurities (I-125 and Te-121) occur for less than 0.05 %.

For this product the effective dose equivalent resulting from an administered activity of 14.8 MBq will be 2.2 mSv. This effective dose equivalent is dependent on the uptake in the thyroid glands.

The table below shows the dosimetry as calculated according to the publication 53 of the ICRP (International Commission of Radiological Protection, Radiation Dose to Patients from Radiopharmaceuticals, Pergamon Press, 1987.)

The effective (whole body) dose equivalent (EDE) is calculated from the six standard organs (gonads, breast, red marrow, lungs, thyroid and bone surfaces) and five additional organs with the highest absorbed dose (marked with *).

(^{123}I) SODIUM IODIDE
Thyroid blocked, uptake 0 %
Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 year	5 year	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
EDE (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

Uptake: 0.5 %	1.6E-02	2.0E-02	3.1E-02	5.2E-02	9.6E-02
Uptake: 1.0 %	1.9E-02	2.5E-02	3.8E-02	6.7E-02	1.3E-01
Uptake: 2.0 %	2.5E-02	3.4E-02	5.2E-02	9.9E-02	1.8E-01

Effect of radionuclidic impurities:
The radionuclidic impurities (^{125}I and ^{121}Te) increase the effective dose equivalent with approximately 0.5 % at reference time and 3 % at expiration time.

(^{123}I) SODIUM IODIDE
Thyroid blocked, uptake 15 %
Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 year	5 year	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
EDE (mSv/MBq)	**7.5E-02**	**1.1E-01**	**1.7E-01**	**3.5E-01**	**6.5E-01**

Effect of radionuclidic impurities:
The radionuclidic impurities (^{125}I and ^{121}Te) increase the effective dose equivalent with approximately 0.6 % at reference time and 4 % at expiration time.

(^{123}I) SODIUM IODIDE
Thyroid blocked, uptake 35 %
Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 year	5 year	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
EDE (mSv/MBq)	**1.5E-01**	**2.3E-01**	**3.5E-01**	**7.4E-01**	**1.4E+00**

Effect of radionuclidic impurities:
The radionuclidic impurities (^{125}I and ^{121}Te) increase the effective dose equivalent with approximately 0.6 % at reference time and 4 % at expiration time.

(^{123}I) SODIUM IODIDE
Thyroid blocked, uptake 55 %
Absorbed dose per unit activity administered (mGy/MBq)

Organ	Adult	15 years	10 year	5 year	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
EDE (mSv/MBq)	**2.3E-01**	**3.5E-01**	**5.3E-01**	**1.1E+00**	**2.1E+00**

Effect of radionuclidic impurities:
The radionuclidic impurities (^{125}I and ^{121}Te) increase the effective dose equivalent with approximately 0.6 % at reference time and 4 % at expiration time.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Solution for intravenous injection, ready to use.

Withdrawals should be performed under aseptic conditions. The vials must not be opened before disinfecting the stopper, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorised automated application system.

If the integrity of this vial is compromised, the product should not be used.

This product is not preserved. After removal of a dose from the vial, store at 2°C-8°C and use within one working day.