PRODUCT INFORMATION

Sodium Iodide (^{131}I) 200MBq/ml Injection

Description

Sodium Iodide (^{131}I) Injection is supplied as a clear, colourless, sterile, non-pyrogenic isotonic solution. The injection solution consists of Sodium Iodide at an activity concentration of 200MBq/ml and sodium thiosulfate at a concentration of 3.35 mg / GBq of I-131 in a phosphate buffered sodium chloride solution. The pH of the injection solution is 7.0 - 8.5. A range of Iodine-131 content is available from 200 to 1600 MBq at the time of calibration at 0900 (Sydney time) on the day of calibration given on the product label.

Activity concentration	Volume	Activity Size	ARTG
200MBq/ml	1-8 ml	200-1600Mbq	22800

The injection solution is contained in a vial made of USP Type 1 glass or an equivalent material and has a 20mm OD neck closed by a 20 mm halo-butyl rubber stopper. The outer container is a labelled lead pot of suitable size to provide adequate shielding.

Physical Characteristics for ^{131}I

Iodine-131 with a physical half-life of 8.04 days, decays by beta emission (average energy 182keV) with associated gamma emission. ^{131}I has a major gamma emission [γ-ray] at 364 keV, although somewhat higher than ideal. The principle beta and gamma photon emissions are listed in Table 1.

Table 1: Principal Radiation Emission Data

Principal Radiation	Mean % per Disintegration	Mean Energy (keV)
Beta-1	2.1	69.4 (Avg.)
Beta-3	7.3	96.6 (Avg.)
Beta-4	89.4	191.5 (Avg.)
Gamma-7	6.1	284.3
Gamma-14	81.2	364.5
Gamma-17	7.3	637.0
Gamma-19	1.8	722.9

Reference: Weber D A, Eckerman K F, Dillman L T and Ryman J C, MIRD: Radionuclide Data and Decay Schemes, The Society of Nuclear Medicine, 1989.

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External Radiation

The specific gamma ray constant for iodine-131 is 0.61 mGy per MBq^{-h} at 1 cm. The first half-value thickness of lead is 0.26 cm and a lead thickness of 2.6cm will produce an attenuation factor of 10^{-2}. A range of values for the relative attenuation of the radiation resulting from the interposition of various thickness of lead [Pb] is shown in Table 2.

Table 2: Radiation Attenuation by Lead Shielding

Shield Thickness (Lead [Pb]) cm	Coefficient of Attenuation
0.26	0.5
0.95	10^{-1}
2.6	10^{-2}
4.6	10^{-3}
6.5	10^{-4}

The fractions that remain at selected intervals for ^{131}I after calibration are listed in Table 3. To correct the effects of physical decay of this radionuclide multiply the activity on the calibration time and date by the appropriate factor from table.

Table 3: Physical Decay Chart for ^{131}I; Half-life 8.04 days

Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
0*	1.00				
1	0.917	8	0.502	15	0.274
2	0.842	9	0.460	16	0.252
3	0.772	10	0.422	17	0.231
4	0.708	11	0.387	18	0.212
5	0.650	12	0.355	19	0.194
6	0.596	13	0.326	20	0.178
7	0.547	14	0.299	21	0.164

***Calibration time**

Pharmacology

Following the administration of the injection, Sodium Iodide (Iodine-131) is rapidly absorbed from the blood stream and distributed into the extra-cellular fluid. A proportion is concentrated by thyroid tissue, where its therapeutic effect is principally due to the beta radiation. Radioiodine taken up by functioning thyroid tissue is incorporated into thyroxine and triiodothyronine; these radioiodinated hormones are metabolised in the liver.

Iodine - 131(^{131}I) is also accumulated by the stomach mucosa, choroids plexus, lactating breast and salivary glands. Most of the remainder is eliminated by renal excretion (60-90%); a small amount is excreted in sweat and saliva.

Diagnostic Examinations:

Sodium Iodide (^{131}I) (physical half-life 8.04 days; gamma emissions 364 keV) could be used in obtaining diagnostic information in adults. In particular, Sodium Iodide (^{131}I) is given intravenously in studies of thyroid function, particularly in measurements of the uptake of iodine by the thyroid, and in thyroid scanning.

Indications

Sodium Iodide (^{131}I) Injection is indicated in the treatment of hyperthyroidism, and the detection of residual functioning thyroid tissue in differentiated thyroid carcinoma.

Contraindications

The use of this therapeutic radiopharmaceutical is absolutely contraindicated in women who are pregnant. Women of reproductive age should have a negative pregnancy test at the time of the radionuclide therapy, and should take appropriate contraceptive measures.

The use of therapeutic iodine-131 is not recommended in persons with renal insufficiency, as delayed excretion will result in increased whole body radiation.

The therapy is contradicted in patients who are being treated concurrently with thyroid hormone or antithyroid drugs, are vomiting or have diarrhoea.

NOTE: "Iodine allergy" is not a contraindication for use, because of the very small chemical amounts of iodine in the injections. (Approx 1 microgram in a 200 MBq dose).

Precautions

(i) General

Radiopharmaceuticals are to be administered only by or under the supervision of physicians who have had extensive training in the safe use and handling of radioactive materials and who are authorized by the appropriate Agreement State agency, if required, or, the appropriate authority.

Disposal of all radioactive wastes should be carried out in accordance with the NH & MRC "Code of practice for the disposal of radioactive wastes by the user" (1985 & 1990).

Adequate hydration of the patient is recommended before and after the examination to promote urinary flow. Also, urination is recommended as often as possible for 4 to 6 hours after the examination to reduce bladder exposure to radiation.

Goitrogenic foods, many medicines and certain diseases (nephrosis, impaired renal function, etc) interfere with the accumulation of radioiodine by the thyroid. Therefore, a careful review of the patient's history, current medications and recent diagnostic tests are required prior to the administration of Sodium Iodide (^{131}I) Injection.

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.

(ii) Hyponatraemia

Serious manifestations of hyponatraemia have been reported after sodium iodide [^{131}I] therapy in elderly patients who have undergone total thyroidectomy. Risk factors include older age, female sex, use of thiazide diuretics and hyponatraemia at the start of sodium iodide [^{131}I] therapy. Regular serum electrolyte measurements and monitoring should be considered for these patients.

Dose Handling:

Radiation exposure to staff must be minimised. In particular the injection should NOT be handled directly. The injection vial may be contaminated externally with iodine-131 and appropriate handling precautions should be used. As iodine-131 is volatile and the daughter radionuclide xenon-131m is gaseous state, the injection vial should be pierced in a ventilated enclosure. (Tests have failed to detect any

diffusion of radioactivity from the injection vial between manufacture and use). The activity of the injection should be checked with a suitable instrument immediately prior to the administration.

Patient Care:
Care should be taken to minimise unwanted radiation exposure to patients, consistent with proper patient management, and to minimise radiation exposure to clinical personnel.

Patients should be encouraged to drink fluids before and after the examination and to void as often as possible after the examination in order to reduce the radiation dose to the kidneys, stomach wall and bladder.

Use During Pregnancy:
See Contraindications.

Use During Lactation:
Iodine-131 is excreted in human milk. If administered to a nursing mother, formula feeding must be substituted.

Interaction with Other Drugs:
The uptake of iodine-131 will be affected by recent intake of stable iodine in any form, e.g. seafood, radiographic contrast media, and by anti-thyroid drugs and thyroxine. The patient's history should by fully investigate in this regard.

Anti-thyroid drugs should be withheld for at least 3 days prior to dose administration and thyroxine should be withdrawn for at least 4 weeks prior to therapy. Adequate trapping of iodide by thyroid tissue or thyroid cancer metastases should be demonstrated before the administration of a therapeutic dose of iodine-131.

Carcinogenesis, Mutagenesis, Impairment Of Fertility

Adequate long-term studies have not been performed in animals to determine whether this drug affects fertility, or has teratogenic or mutagenic potential. Safety and efficacy in children have not been established.

Adverse Reactions

Rare adverse reactions have been reported following the administration of radiopharmaceuticals containing iodine-131, although the effects are unlikely to be associated with the very small chemical amounts of iodine involved. These reactions have included vomiting, nausea, tachycardia, pruritus and rash. When larger doses of iodine-131 are used, reported side effects include radiation thyroiditis and sialitis, and transient worsening of hyperthyroidism. Potential effects of a high dose of iodine-131 include radiation sickness, pulmonary fibrosis, bone marrow depression, acute leukemia, anaemia, acute thyroid crisis and death.

Dosage And Administration

Each vial contains a single dose for intravenous administration and ranges in activity size from 200 MBq to 1600 MBq. **The injection dose range usually employed is as follows:**

Hyperthyroidism: 148 -370MBq for therapy of the adult patients of 70 Kg (Anti-thyroid drugs should be discontinued for 3-4 days prior to the administration of the dose and withheld for 7-14 days afterwards).

Thyroid Imaging: 0.185 – 3.7MBq

Radiation Dosimetry

The estimated absorbed radiation doses to a standard (70 kg) euthyroid patient from an intravenous dose of iodine-131 are shown in the following table:
NB: In a hyperthyroid patient the dose received by the thyroid gland will be well in excess of these readings.

Table 4:
ABSORBED RADIATION DOSE
Per unit activity administered
(mGy per MBq ^{131}I)

	Thyroid Uptake		
Organ	**5%**	**15%**	**25%**
Adrenals	3.2E-02	3.6E-02	3.9E-02
Bladder wall	5.8E-01	5.2E-02	4.6E-01
Bone surface	3.2E-01	4.7E-02	6.1E-02
Breast	3.1E-02	4.3E-02	5.5E-02
Kidneys	6.3E-02	6.0E-02	5.8E-02
Liver	3.0E-02	3.2E-02	3.5E-02
Lung	3.4E-02	5.3E-02	7.2E-02
Ovaries	4.4E-02	4.3E-02	4.3E-02
Pancreas	5.0E-02	5.2E-02	5.3E-02
Red marrow	3.8E-02	5.4E-02	7.0E-02
Spleen	3.9E-02	4.2E-02	4.4E-02
Testes	2.9E-02	2.8E-02	2.7E-02
Thyroid	7.2E+01	2.1E+02	3.6E+02
Uterus	5.5E-02	5.4E-02	5.2E-02
Other tissue	4.0E-02	6.5E-02	9.0E-02
Effective dose (mSv/MBq)	3.7E+00	1.1E+01	1.8E+01

References:
ICRP publication 53, Radiation Dose to Patients from Radiopharmaceuticals (1988). Vol 18, No.1-4 pp 276. Pergamon, Oxford, 1988.

ICRP publication 60, 1990 Recommendations for the International Commission on Radiological Protection. Pergamon, Oxford, p7-8, 1991.

Overdosage

Treatment of over dosage should be symptomatic and consist of general supportive measures.

Contact Poisons Information Centre on 13 11 26 for advice on management overdose.

Presentation

The injection solution is contained in 10 ml serum vial made of USP Type 1 glass or an equivalent material and has a 20mm OD neck closed by a 20 mm halo-butyl rubber stopper. The outer container is a labelled lead pot of suitable size to provide adequate shielding.

Sodium Iodide (^{131}I) Injection are supplied as a single dose of 200-1600 MBq at the time of calibration of 0900 hrs (Sydney time) each Wednesday.

Poison Schedule of the Medicine:

Radiopharmaceutical.

Expiry

The injection has an expiry time of 14 days from the calibration date as shown on the pack and should not be used after expiry.

Storage

Store below 25°C. Do not freeze.

Store in an airtight container in a place that is sufficiently shielded to protect personnel from irradiation by primary or secondary emission and that complies with national and international regulations concerning the storage of radioactive substances.

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