Sodium Iodide (^{131}I) Solution BP (for therapy)

be uncapped in a ventilated enclosure.

(iv) Administer to patient followed by a drink of water.

(v) Treat gloves, the empty vial, stopper and caps as active waste

Radiation Dosimetry

The estimated absorbed radiation doses to a standard (70 kg) euthyroid patient from an oral dose of iodine-131 are shown in table 4.

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 (mGy per MBq ^{131}I)

Tissue	Thyroid Uptake		
	5%	15%	25%
Thyroid	72.0	210.0	360.0
Stomach Wall	0.45	0.46	0.46
Red Marrow	0.038	0.054	0.070
Liver	0.030	0.032	0.035
Testes	0.029	0.028	0.027
Ovaries	0.044	0.043	0.043
Kidneys	0.063	0.060	0.058
Effective Dose Equivalent (mSv/MBq)	2.3E+00	6.6E+00	1.1E+01

Reference: ICRP.53 - Radiation Dose to Patients from Radiopharmaceuticals, Vol.18, No.1-4, 1987.

Presentation

Sodium Iodide (^{131}I) Solution BP (for therapy) is supplied in sealed 10 mL glass vials in a lead container of appropriate thickness.

Expiry

Expiry date is printed on the product vial label.

Storage

Store below 25°C.

Date amended: July 2018
TGA Approval Date: 11 July 2018

AUST R No: 22807 (200 MBq/mL)
AUST R No: 48267 (2000 MBq/mL)

Product No: 10019 50MBq – 1200MBq
10234 1201MBq – 16,000MBq

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Ansto Health

PRODUCT INFORMATION

Sodium Iodide (^{131}I) Solution BP (for therapy)

Description

Sodium Iodide [^{131}I] Solution BP (for therapy) is supplied for oral administration as a colourless solution containing sodium iodide [^{131}I]. A range of Iodine-131 content is available from 50 MBq to 16000 MBq at the time of calibration at 0900 hrs (Sydney time) each Monday.
The solution is contained in a 10ml glass serum vial sealed with a rubber stopper and aluminium seal. The vial is in turn contained in a lead pot. The product is designed for therapy use.

Physical Characteristics of (^{131}I)

Iodine-131 decays by beta and gamma emission with a physical half-life of 8.04 days. The principal beta emissions and gamma photons 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.

TABLE 2: Physical Decay Chart for [^{131}I]

Days	Fraction remaining	Days	Fraction remaining
0	1.000	15	0.274
1	0.917	16	0.252
2	0.842	17	0.231
3	0.772	18	0.212
4	0.708	19	0.194
5	0.650	20	0.178
6	0.596	21	0.164
7	0.547	22	0.150
8	0.502	23	0.138
9	0.460	24	0.126
10	0.422	25	0.116
11	0.387	26	0.106
12	0.355	27	0.098
13	0.326	28	0.089
14	0. 299		

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 for iodine-131 is 0.26 cm. Attenuation by lead is given in Table 3

Table 3: Radiation Attenuation by lead shielding

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

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Sodium Iodide (^{131}I) Solution BP (for therapy)

Pharmacology
Following oral administration of the solution, sodium iodide (^{131}I) is rapidly absorbed from the gastrointestinal tract into the bloodstream and distributed in the extracellular fluid. A proportion is concentrated by thyroid tissue, where its therapeutic effect is principally due to the beta radiation. Some iodine is also trapped by the stomach and salivary glands. Most of the remainder is eliminated by renal excretion, a small amount is excreted in sweat and saliva. Radioiodine taken up by functioning thyroid tissue is incorporated into thyroxine and triiodothyronine; these radioiodinated hormones are metabolised in the liver.

Indications
Sodium Iodide (^{131}I) Solution BP (for therapy) is indicated in the treatment of hyperthyroidism's, and the detection and ablation 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 radionuclide therapy, and should take appropriate contraceptive measures.

This therapy is contraindicated in patients who are vomiting or have diarrhoea or who are being treated concurrently with thyroid hormone or antithyroid drugs.
The use of therapeutic iodine-131 is not recommended in persons with renal insufficiency, as delayed excretion will result in increased whole body radiation.

Note "Iodine allergy" is not a contraindication for use, because of the very small chemical amounts of iodine in therapeutic solutions.

Warning
Iodine-131 should not be administered to individuals below the age of 18 years unless such use is essential in the judgement of the clinician and the benefits outweigh any potential risk.

Precautions
(i) General
Radiopharmaceuticals should be used only by physicians who are qualified and licensed to handle radioisotopes.

(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. The glass vial containing the solution 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, the vial containing the solution should be uncapped in a ventilated enclosure. (Tests have failed to detect any diffusion of radioactivity from the sealed glass vial between manufacture and use). The activity of the solution should be checked with a suitable instrument immediately prior to administration.

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.

Sodium Iodide (^{131}I) Solution BP (for therapy)

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

Patients should be encouraged to drink copious fluids before and after solution administration and to void as often as possible after administration in order to reduce the radiation dose to the kidneys, stomach and bladder. A high standard of patient hygiene is desirable. In Australia, isolation care is currently recommended by the NH&MRC for patients carrying more than 600 MBq of iodine-131. Since iodine-131 is secreted in saliva, intimate contact between patients and children should be avoided (for 10 days) following a therapeutic dose.

Use during Pregnancy
SEE CONTRAINDICATIONS. Ideally procedures using radiopharmaceuticals in women of childbearing age, especially those of an elective nature, should be performed during the first few days (approx 10) following the onset of menses.

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, eg, seafood, radiographic contrast media, and by anti-thyroid drugs and thyroxine. The patient's history should by fully investigated 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.

Long-term Effects
Therapy using iodine-131 can induce hypothyroidism. To some extent this effect is dose dependent, but life-long follow-up of patients treated with iodine-131 is advised.

Carcinogenesis Mutagenesis Impairment of Fertility
Adequate long term studies have not been performed in animals to determine whether this drug affects fertility, or has terogenic or mutagenic potential. Safety and efficacy in children have not been established.

Adverse Reactions
Rare adverse reactions have been reported following the administration of iodine-131. Their relationship to the very small chemical amounts of iodine administered is not clear. These reactions have included vomiting, nausea, tachycardia, pruritus and rash. Other reported side effects include radiation thyroiditis and sialitis, and transient worsening of hypothyroidism.

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.

Dose and Administration
The solution is for oral administration and the dose ranges usually employed are as follows:

Thyrotoxicosis	150-600	MBq
Thyroid ablation	800-2000	MBq
Thyroid carcinoma	2000-6000	MBq

The recommended procedure for dose administration is as follows:
(i) Check expiry date of solution.
(ii) Measure the activity of the solution while still in the sealed glass vial.
(iii) The vial containing the solution should