PRODUCT INFORMATION

ANSTO - Sodium Iodide [131I] Therapy Capsules (50 to 6000 MBq)

Description

Sodium Iodide [^{131}I] Therapy Capsules are supplied for oral administration as pale yellow gelatin capsules containing sodium iodide [^{131}I] solution adsorbed on an inert filler (anhydrous di-sodium hydrogen phosphate). Other excipients include sodium bicarbonate solution and water for Injection. A range of iodine-131 content is available, from 50 MBq to 6000MBq at the time of calibration at 0900 hrs (Sydney time) each Monday.

Each capsule is contained in a glass serum vial sealed with a rubber stopper and red aluminium seal. The vial is in turn contained in an appropriate lead container. A special lead shielded decapping pot and decapping pliers are supplied free with the initial order.

Physical Characteristics of [^{131}I]

Iodine-131 with a physical half-life of 8.04 days, decays by beta emission (average energy 182 keV) with associated gamma emission. Stable xenon-131 is formed in 98.9% of decays and radioactive xenon -131m (half-life 11.9 days) in 1.1% of decays. 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)
Beta1	2.1	69.4 (Avg.)
Beta3	7.3	96.6 (Avg.)
Beta4	89.4	191.5 (Avg.)
Gamma7	6.1	284.3
Gamma14	81.2	364.5
Gamma17	7.3	637.0
Gamma19	1.8	722.9

Reference: Weber DA, Eckerman KF, Dillman LTand Ryman J C, MIRD: Radionuclide Data and Decay Schemes, The Society of Nuclear Medicine,1989.

Table2: Physical Decay Chart for[^{131}I]

Days	Fraction Remaining	Days	Fraction Remaining
0	1.000	8	0.502
1	0.917	9	0.460
2	0.842	10	0.422
3	0.772	11	0.387
4	0.708	12	0.355
5	0.650	13	0.326
6	0.596	14	0.299
7	0.547		

External Radiation
The specific gamma ray constant for iodine-131 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 about $10^{-2.}$ Attenuation by lead is given in Table 3.

Table 3: Principal Radiation Emission Data

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}

Pharmacology
The ATC code of NaI capsules is:
Therapeutic radiopharmaceuticals, sodium [131-I] iodine
ATC Code: V 10X A01

Following oral administration of the capsule, sodium iodide (131I) 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-131 is trapped by the choroid plexus, stomach and salivary glands. Most of the remainder is eliminated by renal excretion; a small amount is excreted in sweat and saliva. Iodine-131 taken up by functioning thyroid tissue is incorporated into thyroxine and triiodothyronine; these radioiodinated hormones are metabolised in the liver.
Iodide in the amount used for therapeutic indications, is not known to have any pharmacological effect. More than 90 % of the radiation effects result from beta radiation which has a mean range of 0.5 mm.

> **Note:** As with other iodine-131 gelatin capsules, some iodine-131 is lost due to binding of iodine-131 to the capsule material. This iodine-131 does not appear to be available for uptake by the thyroid.

Indications
Sodium Iodide (^{131}I) Therapy Capsules are indicated in the treatment of hyperthyroidism, 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.

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

This therapy is contraindicated 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 therapy capsules (e.g. approx.3 microgram in a 500 MBq capsule).

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 risks.

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. In particular the capsules should NOT be handled directly. The glass vial containing the capsule 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 capsule 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 capsule 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 and MRC "Code of Practice for the Disposal of Radioactive Wastes by the User" 1985.

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 copious fluids before and after capsule administration and to void as often as possible after administration in order to reduce the radiation dose to the kidneys, stomach wall 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.

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 antithyroid drugs and thyroxine. The patient's history should be fully investigated in this regard.

Antithyroid drugs should be withheld for at least 3 days prior to iodine-131 therapy, 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 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 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-induced 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.

Overdose and Treatment
In case of overdose, the risk of high radiation exposure may exist. As the medicinal product is excreted through the kidneys, the overdose of radiation exposure can be reduced by forced diuresis and frequent bladder voiding. Additionally, the blockade of the thyroid gland should be recommended (e.g. with potassium iodide or perchlorate) immediately following suspected overexposure in order to reduce the radiation exposure of the thyroid gland. To reduce the uptake of I-131, emetics can be given.

Dose and Administration
The capsules are 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 (in two capsules)

Instructions for Use
(i) Prepare disposable gloves for staff and patient, absorbent paper tissues, empty disposable paper cup and a drink of water in a disposable paper cup.

(ii) Check expiry date of capsule, remove lid of lead container.

(iii) Measure the activity of the capsule while still in the sealed glass vial.

(iv) Check that lead shielded decapping pot (supplied with initial order) has a bottle retaining spring inside it. Using forceps, transfer the sealed glass vial to the decapping pot.

(v) In a suitably ventilated enclosure remove the cap and closure from the glass vial, while still in the lead container, with the decapping pliers supplied. (The cap should be gripped in the modified jaws of the pliers and then squeezed as hard as possible before twisting the cap and closure off).

(vi) Pick up the decapping pot and tip the capsule into the empty disposable paper cup. Using forceps, replace the empty vial and closure in the lead container used for shipment.

Note: The empty vial and closure should be remeasured to confirm that no significant loss of activity has occurred from the capsule during transport and storage.

(vii) Present both disposable paper cups to the patient who should then swallow the capsule and take a drink of water if necessary. The patient should be advised not to bite the capsule.

(viii) Treat gloves, cups and the empty vial, stopper and cap 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 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 (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.14,1987.

Presentation
Sodium Iodide [^{131}I] Therapy Capsules are supplied individually in sealed 10 mL glass vials in a lead container of appropriate thickness.

A range of iodine-131 content is available, from 50 MBq to 6000 MBq at the time of calibration, at 0900 hrs (Sydney time) each Monday.

Not all presentations may be available locally.

Expiry
Refer to outer label.

Storage
Refer to outer label.

Last revised
Dec 2020

Product No: 10020: 50MBq – 600MBq
10233: 700MBq – 6000MBq

Product registrant
Transmedic Pte Ltd
5 Jalan Kilang Barat, #09-00 Floor Petro Centre,
Singapore 159349

Australian Government | ANSTO