Sodium Iodide I 131 Solution Rx Only.

DESCRIPTION

Sodium Iodide I 131 ($Na^{131}I$) for therapeutic use is available as a stabilized aqueous solution for oral administration. The solution is available in screw-cap vials with radioactivity ranging from 129.5 to 5550 megabecquerels (3.5 to 150 millicuries) per vial at the time of calibration. The solution contains 0.1% sodium bisulfite and 0.2% edetate disodium as stabilizers, 0.5% sodium phosphate anhydrous as a buffer and sodium iodide I 131 at concentrations of 129.5, 185, or 925 megabecquerels (3.5, 5.0, or 25.0 millicuries) per milliliter. The pH has been adjusted to between 7.5 and 9.0. The iodine I 131 utilized in the preparation of the solution contains not less than 99% iodine I 131 at the time of calibration.

PHYSICAL CHARACTERISTICS

Iodine I 131 decays by beta emission and associated gamma emission with a physical half-life of 8.04 days[1]. The principal beta emissions and gamma photons are listed in Table 1.

Table 1. Principal Radiation Emission Data

Radiation	Mean Percent Per Disintegration	Energy (keV)
Beta-1	2.12	69.4 Avg.
Beta-3	7.36	96.6 Avg.
Beta-4	89.3	191.6 Avg.
Gamma-7	6.05	284.3
Gamma-14	81.2	364.5
Gamma-17	7.26	637.0

EXTERNAL RADIATION

The specific gamma ray constant for iodine I 131 is 2.27 R/hr-mCi at 1 cm. The first half-value thickness of lead (Pb) for iodine I 131 is 0. 24 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 4.6 cm of Pb will decrease the external radiation exposure by a factor of about 1,000.

Table 2. Radiation Attenuation by Lead Shielding[2]

Shield Thickness (Pb), cm	Coefficient of Attenuation
0.24	0.5
0.95	10^{-1}
2.6	10^{-2}
4.6	10^{-3}
6.5	10^{-4}

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the date of calibration are shown In Table 3.

Table 3. Physical Decay Chart, Iodine I 131, Half-Life 8.04 Days

Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	16	0.252
1	0.917	17	0.231
2	0.842	18	0.212
3	0.772	19	0.194
4	0.708	20	0.178
5	0.650	21	0.164
6	0.596	22	0.150
7	0.547	23	0.138
8	0.502	24	0.126
9	0.460	25	0.116
10	0.422	26	0106
11	0.387	27	0.098
12	0.355	28	0.089
13	0.326	29	0.082
14	0.299	30	0.075
15	0.274		

* Calibration Day

[1] Kocher, David C., "Radioactive Decay Data Tables," DOE/TIC 11026, page 133 (1981).

[2] Data supplied by Oak Ridge Associated Universities, Radiopharmaceutical Internal Dose Information Center, Oak Ridge, TN, 1987.

CLINICAL PHARMACOLOGY

Sodium Iodide is readily absorbed from the gastrointestinal tract. Following absorption, the iodide is distributed primarily within the extracellular fluid of the body. It is concentrated and organified by the thyroid, and trapped but not organified by the stomach and salivary glands. It is also promptly excreted by the kidneys. About 90% of local irradiation is the result of beta radiation and 10% is the result of gamma radiation.

INDICATIONS AND USAGE

Sodium Iodide I 131 Therapeutic may be indicated in the treatment of hyperthyroidism and selected cases of carcinoma of the thyroid. Palliative effects may be seen in patients with papillary and/or follicular carcinoma of the thyroid. Stimulation of radioiodide uptake may be achieved by the administration of thyrotropin. (Radioiodide will not be taken up by giant cell and spindle cell carcinoma of the thyroid nor by amyloid solid carcinomas.)

CONTRAINDICATIONS

Vomiting and diarrhea represent contraindications to the use of radioiodide.

Therapeutic doses of Sodium Iodide I 131 may cause fetal harm when administered to a pregnant woman. Therapeutic doses of Sodium Iodide I 131 are contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazards to the fetus.

WARNINGS

Contains sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Sodium Iodide I 131 is not usually used for treatment of hyperthyroidism in patients under 30 years of age.

PRECAUTIONS

General

The uptake of radioiodide will be affected by recent intake of stable iodine in any form, or by the use of thyroid, anti-thyroid, and certain other drugs. Accordingly, the patient should be questioned carefully regarding previous medication and procedures involving radiographic contrast media.

The expiration date is not later than one month after the calibration date. The calibration date and the expiration date are stated on the label.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential, or whether this drug affects fertility in males or females.

Pregnancy Category X

See CONTRAINDICATIONS section.

Radioiodide therapy in women of childbearing capability should only be performed when appropriate contraceptive measures have been taken or when pregnancy testing is negative.

Nursing Mothers

Radioiodine is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

See WARNINGS Section.

ADVERSE REACTIONS

Although rare, reactions have been reported following the administration of iodine-containing radiopharmaceuticals including, in decreasing order of frequency, nausea, vomiting, chest pain, tachycardia, itching skin, rash, and hives. Depression of the hematopoietic system may occur when large doses are employed. Such potential side effects include radiation sickness, increase in clinical symptoms, bone marrow depression, acute leukemia, anemia, chromosomal abnormalities, acute thyroid crisis, blood dyscrasia, leukopenia, thrombocytopenia, and death.

DOSAGE AND ADMINISTRATION

Antithyroid therapy of a severely hyperthyroid patient is usually discontinued three to four days before administration of radioiodide.

For hyperthyroidism, the usual dose range is 148 to 370 megabecquerels (4 to 10 millicuries). Toxic nodular goiter and other special situations will require the use of larger doses.

For thyroid carcinoma, 1850 megabecquerels (50 millicuries) is the usual dose for ablation of normal thyroid tissue, and 3700 to 5550 megabecquerels (100 to 150 millicuries) is the usual subsequent therapeutic dose.

Waterproof gloves should be used during the entire handling and administration procedure. Adequate shielding should be maintained during the life of the product.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

RADIATION DOSIMETRY

The estimated absorbed radiation doses[3] to an average (70 kg) euthyroid (normal functioning thyroid) patient from an oral dose of iodine I 131 in both milligrays per megabecquerel and rads per millicurie are shown in Table 4.

Table 4. Absorbed Radiation Doses

Tissue	Thyroid Uptake					
	5%		15%		25%	
	mGy/ MBq	rads/ mCi	mGy/ MBq	rads/ mCi	mGy/ MBq	rads/ mCi
Thyroid	70.3	260	216.2	800	351.4	1300
Stomach Wall	0.459	1.7	0.432	1.6	0.378	1.4
Red Marrow	0.038	0.14	0.054	0.20	0.070	0.26
Liver	0.054	0.20	0.095	0.35	0.130	0.48
Testes	0.023	0.084	0.023	0.085	0.024	0.088
Ovaries	0.038	0.14	0.038	0.14	0.038	0.14
Total Body	0.065	0.24	0.127	0.47	0.192	0.71

[3] MIRD DOSE ESTIMATE REPORT No. 5 Summary and Current Radiation Dose Estimates to Humans from ^{123}I, ^{124}I, ^{125}I, ^{126}I, ^{130}I, ^{131}I, and ^{132}I, Sodium Iodide. J. Nucl. Med., 16, No. 9, 857-60 (1975).

HOW SUPPLIED

Catalog Number 450.

Sodium Iodide I 131 solution for therapeutic use by oral administration is available in shielded, screw-cap vials containing the following quantities of iodine I 131.

Concentration*	Volume of Solution	Total Radioactivity* per Vial
129.5 MBq/mL (3.5 mCi/mL)	1 mL 2 mL	129.5 MBq (3.5 mCi) 259 MBq (7 mCi)
185 MBq/mL (5.0 mCi/mL)	1 mL 2 mL 3 mL 4 mL 5 mL 7 mL	185 MBq (5 mCi) 370 MBq (10 mCi) 555 MBq (15 mCi) 740 MBq (20 mCi) 925 MBq (25 mCi) 1295 MBq (35 mCi)
925 MBq/mL (25.0 mCi/mL)	2 mL 3 mL 4 mL 6 mL	1850 MBq (50 mCi) 2775 MBq (75 mCi) 3700 MBq (100 mCi) 5550 MBq (150 mCi)

* At Time of Calibration

STORAGE AND HANDLING

Sodium Iodide I 131 Therapeutic Solution should be stored at controlled room temperature 20°-25°C (68°-77°F).

Storage and disposal of Sodium Iodide I 131 Solution should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

The U.S. Nuclear Regulatory Commission has approved distribution of this radiopharmaceutical to persons licensed to use by-product material listed in Section 35.300, and to persons who hold an equivalent license issued by an Agreement State.

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Mallinckrodt Inc.
St. Louis, MO 63134

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