Sodium Iodide I 131 Capsules Diagnostic

Rx Only.

DESCRIPTION

Sodium Iodide 131 (Na ^{131}I) for diagnostic use is supplied for oral administration in opaque white gelatin capsules. The capsules are available in a strength of 3.7 megabecquerels (100 microcuries) iodine I-131 at the time of calibration.

Sodium Iodide I 131 Capsules are prepared by absorbing a solution of carrier-free sodium iodide I-131 into inert fillers. The iodine I-131 utilized in the preparation of the capsules contains not less than 99% iodine I-131 at the time of calibration.

PHYSICAL CHARACTERISTICS

Iodine I-131 decays by beta and associated gamma emissions with a physical half-life of 8.04 days.[1] The principle 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	0.106
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.

Indications and Usage

Sodium Iodide I 131 is indicated for use in performance of the radioactive iodide (RAI) uptake test to evaluate thyroid function. Diagnostic doses may also be employed in localizing metastases associated with thyroid malignancies.

CONTRAINDICATIONS

None.

WARNINGS

None.

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 two months from the date of manufacture. The calibration date and the expiration date are stated on the container 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, Mutageneses, 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 C

Animal reproduction studies have not been conducted with Sodium Iodide I 131 Diagnostic Capsules. It is also not known whether Sodium Iodide I 131 Diagnostic Capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Iodide I 131 Diagnostic Capsules should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceutical drug products — especially those elective in nature — of women of childbearing capability should be performed during the first ten days following the onset of menses.

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Although rare, reactions associated with the administration of iodine containing radiopharmaceuticals for diagnostic use include, in decreasing order of frequency, nausea, vomiting, chest pain, tachycardia, itching skin, rash and hives.

DOSAGE AND ADMINISTRATION

The suggested oral dosage ranges employed in the average patient (70 kg) for diagnostic procedures for thyroid function are as follows:

Thyroid Uptake: 0.185 to 0.555 megabecquerels (5 to 15 microcuries)

Scintiscanning: 1.85 to 3.7 megabecquerels (50 to 100 microcuries)

Localization of extra-thyroidal metastases: 37 megabecquerels (1000 microcuries).

Waterproof gloves should be used during the entire handling and administration procedure.

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 3.7 megabecquerels (100 microcuries) of iodine I-131 are shown in Table 4.

Table 4. Absorbed Radiation Doses

Tissue	Absorbed radiation doses for 3.7 megabecquerels (100 Microcuries)					
	Thyroid Uptake					
	5%		15%		25%	
	mGy	rads	mGy	rads	mGy	rads
Thyroid	260	26.0	800	80.0	1300	130.0
Stomach Wall	1.7	0.17	1.6	0.16	1.4	0.14
Red Marrow	0.14	0.014	.20	0.020	0.26	0.026
Liver	0.20	0.020	0.35	0.035	0.48	0.048
Testes	0.08	0.008	0.09	0.009	0.09	0.009
Ovaries	0.14	0.014	0.14	0.014	0.14	0.014
Total Body	0.24	0.024	0.47	0.047	0.71	0.071

HOW SUPPLIED

Catalog Number 300.

Sodium Iodide I 131 Diagnostic Capsules are supplied in a strength of 3.7 megabecquerels (100 microcuries) at time of calibration. The capsules are packaged in plastic vials containing 5, 10, or 15 capsules per vial.

STORAGE AND HANDLING

Sodium Iodide I 131 Diagnostic capsules should be stored at controlled room temperature 20-25°C (68-77°F) [See USP].

Storage and disposal of Sodium Iodide I 131 Diagnostic Capsules 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 byproduct material listed in Section 35.100, and to persons who hold an equivalent license by an Agreement State.

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[3] MIRD DOSE ESTIMATE REPORT No. 5. Summary of 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).