Sodium Iodide I-123 Capsules

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Sodium Iodide I-123 Capsules

601, 602

A601I0

Diagnostic—For Oral Administration

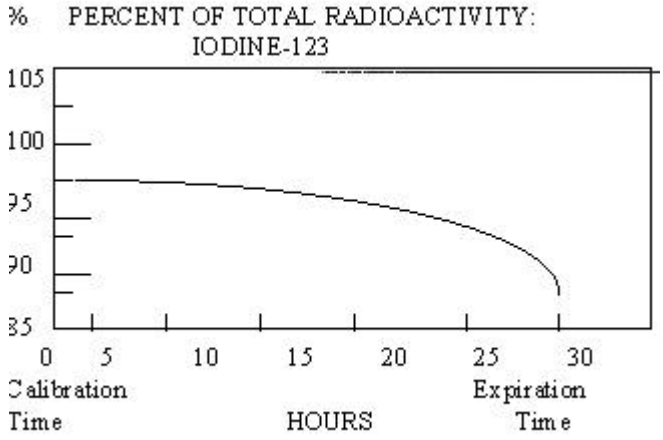
Revised 7/95

DESCRIPTION

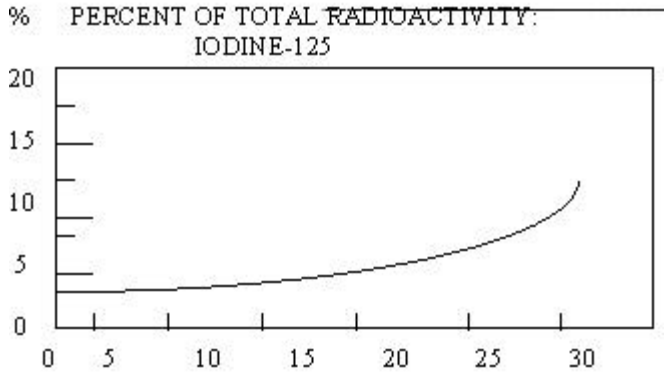
Sodium Iodide I-123 (Na ^{123}I) for diagnostic use is supplied in capsules for oral administration. The capsules are available in strengths of 3.7 and 7.4 megabecquerels (MBq) (100 and 200 μCi) I-123 at time of calibration.

The radionuclidic composition at calibration is not less than 97.0 percent I-123, not more than 2.9 percent I-125 and not more than 0.1 percent Te-121. The radionuclidic composition at expiration time is not less than 87.2 percent I-123, not more than 12.4 percent I-125 and not more than 0.4 percent Te-121. The ratio of the concentration of I-123 and I-125 changes with time. Graph 1 shows the minimum concentration of I-123 as a function of time and Graph 2 shows the maximum concentration of I-125 as a function of time.

Graph 1. Radionuclidic Concentration of I-123



Graph 2. Radionuclidic Concentration of I-125



PHYSICAL CHARACTERISTICS

Iodine-123 decays by electron capture with a physical half-life of 13.2 hours[1]. The photon that is useful for detection and imaging studies is listed in Table 1.

Table 1. Principal Radiation Emission Data[1]

Radiation	Mean % Disintegration	Energy (keV)
Gamma-2	83.4	159

EXTERNAL RADIATION

The specific gamma ray constant for I-123 is 1.6 R/hr-mCi at 1 cm. The first half-value thickness of lead (Pb) for I-123 is 0.005 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 1.63 cm of lead will decrease the external radiation exposure by a factor of about 1,000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb), cm	Coefficient of Attenuation
0.005	0.5
0.10	10^{-1}
0.88	10^{-}
1.63	10^{-32}
2.48	10^{-4}

Note that these estimates of attenuation do not take into consideration the presence of radionuclidic contaminants.

To correct for physical decay of I-123, the fractions that remain at selected intervals after the time of calibration are shown in Table 3.

Table 3. Iodine I-123 Decay Chart:
Half-Life 13.2 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	18	0.389
3	0.854	21	0.332
6	0.730	24	0.284
9	0.623	27	0.242
12	0.533	30	0.207
15	0.455		

*Time of Calibration

CLINICAL PHARMACOLOGY

Sodium Iodide I-123 is readily absorbed from the upper gastrointestinal tract. Following absorption, the iodide is distributed primarily within the extracellular fluid of the body. It is trapped and organically bound by the thyroid and concentrated by the stomach, choroid plexus and salivary glands. It is excreted by the kidneys.

The fraction of the administered dose which is accumulated in the thyroid gland may be a measure of thyroid function in the absence of unusually high or low iodine intake or administration of certain drugs which influence iodine accumulation by the thyroid gland. Accordingly, the patient should be questioned carefully regarding previous medications and/or procedures involving radiographic media. Normal subjects can accumulate approximately 10 to 50% of the administered iodine dose in the thyroid gland, however, the normal and abnormal ranges are established by individual physician's criteria. The mapping

(imaging) of Sodium Iodide I-123 distribution in the thyroid gland may provide useful information concerning thyroid anatomy and definition of normal and/or abnormal functioning of tissue within the gland.

INDICATIONS AND USE

Administration of Sodium Iodide I-123 is indicated as a diagnostic procedure to be used in evaluating thyroid function and/or morphology.

CONTRAINDICATIONS

To date there are no known contraindications to the use of Sodium Iodide I-123 capsules.

WARNINGS

Females of childbearing age and pediatric patients should not be studied unless the benefits anticipated from the performance of the test outweigh the possible risk of exposure to the amount of ionizing radiation associated with the test.

PRECAUTIONS

General

The contents of the capsule are radioactive. Adequate shielding of the preparation must be maintained at all times.

Do not use after the expiration time and date stated on the label.

The prescribed Sodium Iodide I-123 dose should be administered as soon as practical from the time of receipt of product (i.e., as close to calibration time as possible), in order to minimize the fraction of radiation exposure due to the relative increase of radionuclidic contaminants with time.

Sodium Iodide I-123, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

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 government 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 Sodium Iodide I-123 affects fertility in males or females.

Pregnancy Category C

Animal reproduction studies have not been conducted with this drug. It is also not known whether Sodium Iodide I-123 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Iodide I-123 should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of child-bearing capability should be performed during the first few (approximately ten) days following the onset of menses.

Nursing Mothers

Since I-123 is excreted in human milk, formula-feeding should be substituted for breast-feeding if the agent must be administered to the mother during lactation.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Table 4. Absorbed Radiation Dose Estimates as a Function of Maximum Thyroid Uptake for Sodium Iodide I-123[1] At Time of Calibration and Expiry Compared to Sodium Iodide I 131

		Estimated Radiation Absobed Doses		
		I-123 mGy/14.8 MBq (rads/400 μCi)	I-131 mGy/3.7 MBq (rads/100 μCi)	
Maximum Target Organ	Thyroid Uptake (%)	TOC	TOE	
Bladder[2]	5	1.7 (0.17)	1.7 (0.17)	2.9 (0.29)
	15	1.6 (0.16)	1.6 (0.16)	2.7 (0.27)
	25	1.4 (0.14)	1.5 (0.15)	2.4 (0.24)
Stomach Wall	5	0.96 (0.096)	0.98 (0.098)	1.7 (0.17)
	15	0.89 (0.089)	0.91 (0.091)	1.5 (0.15)
	25	0.82 (0.082)	0.85 (0.085)	1.4 (0.14)
Small Intestine	5	0.70 (0.070)	0.71 (0.071)	1.2 (0.12)
	15	0.65 (0.065)	0.67 (0.067)	1.1 (0.11)
	25	0.60 (0.060)	0.62 (0.062)	0.99 (0.099)
Liver	5	0.089 (0.0089)	0.13 (0.013)	0.16 (0.016)
	15	0.10 (0.010)	0.18 (0.018)	0.28 (0.028)
	25	0.11 (0.011)	0.24 (0.024)	0.41 (0.041)
Ovaries	5	0.18 (0.018)	0.19 (0.019)	0.18 (0.018)
	15	0.17 (0.017)	0.18 (0.018)	0.18 (0.018)
	25	0.16 (0.016)	0.18 (0.018)	0.17 (0.017)
Skeleton	5	0.11 (0.011)	0.16 (0.016)	0.12 (0.012)
	15	0.12 (0.012)	0.18 (0.018)	0.18 (0.018)
	25	0.14 (0.014)	0.21 (0.021)	0.24 (0.024)
Red Marrow	5	0.12 (0.012)	0.16 (0.016)	0.15 (0.015)
	15	0.12 (0.012)	0.18 (0.018)	0.21 (0.021)
	25	0.13 (0.013)	0.19 (0.019)	0.27 (0.027)
Testes	5	0.076 (0.0076)	0.089 (0.0089)	0.12 (0.012)
	15	0.072 (0.0072)	0.087 (0.0087)	0.12 (0.012)
	25	0.068 (0.0068)	0.085 (0.0085)	0.12 (0.012)
Thyroid	5	25 (2.5)	75 (7.5)	260 (26)
	15	77 (7.7)	230 (23)	780 (78)
	25	130 (13)	410 (41)	1300 (130)
Total Body	5	0.11 (0.011)	0.16 (0.016)	0.24 (0.024)
	15	0.14 (0.014)	0.25 (0.025)	0.47 (0.047)
	25	0.17 (0.017)	0.35 (0.035)	0.70 (0.070)

[1] Concentration at Time of Calibration: 97% I-123, 2.9% I-125, 0.1% Te-1210
Concentration at Time of Expiry: 87.2% I-123, 12.4% I-125, 0.4% Te-121
Metabolic model in MIRD Dose Estimate Report 5 followed for I-123 and I-125

Metabolic model in ICRP 30 followed for Te-121

[2] Bladder voiding interval 4.8 hours.

HOW SUPPLIED

Catalog Number 601, 602.
Sodium Iodide I-123 is supplied as capsules for oral administration in strengths of 3.7 MBq (100 µCi) (red and white) and 7.4 MBq (200 µCi) (green and white) at time of calibration. Each gelatin capsule contains sucrose as a filler. The capsules are packaged in plastic vials containing either one, three or five capsules of a single strength per vial. The plastic vial is packaged in a lead shield. A package insert is supplied with each lead shield.

STORAGE AND HANDLING
The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained.

Dispense and preserve capsules in tightly-closed containers that are adequately shielded. Store at room temperature (15°C to 30°C).

Storage and disposal of Sodium Iodide I-123 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.

[1] Kocher, David C., Radioactive Decay Data Tables. DOE/TIC-11026,122 (1981)

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