

SODIUM IODIDE I 123- sodium iodide i 123 capsule, gelatin coated
Curium US LLC

Sodium Iodide I 123 Capsules

Rx only

Diagnostic - For Oral Administration

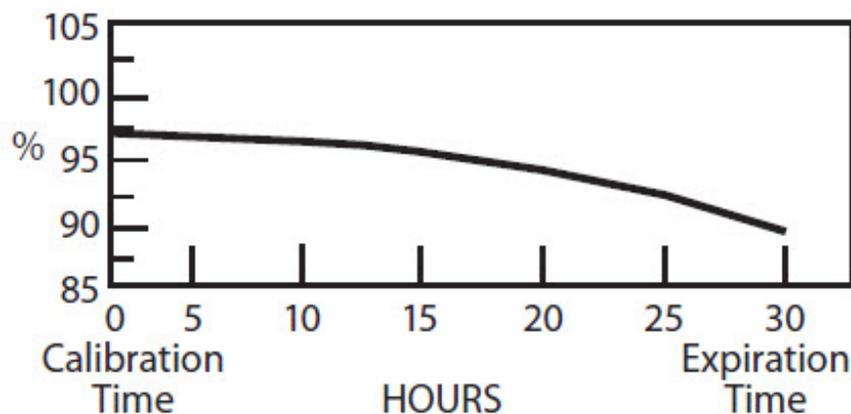
DESCRIPTION

Sodium Iodide I 123 ($\text{Na } ^{123}\text{I}$) 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.

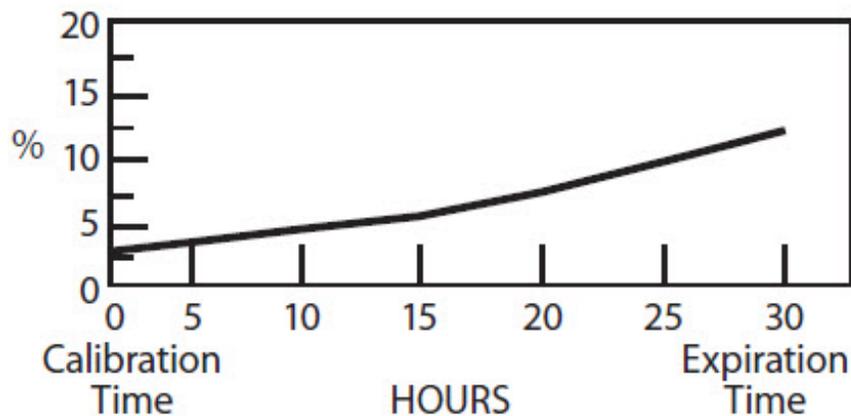
Graph 1. Radionuclidic Concentration of I-123

PERCENT OF TOTAL RADIOACTIVITY:
IODINE-123



Graph 2. Radionuclidic Concentration of I-125

PERCENT OF TOTAL RADIOACTIVITY:
IODINE-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

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

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

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^{-2}
1.63	10^{-3}
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 USAGE

Administration of Sodium Iodide I 123 Capsules 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.

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

The recommended oral dose for the average patient (70 kg) is 3.7 to 14.8 MBq (100 to 400 μ Ci). The lower part of the dosage range 3.7 MBq (100 μ Ci) is recommended for uptake studies alone, and the higher part 14.8 MBq (400 μ Ci) for thyroid imaging. The determination of I-123 concentration in the thyroid gland may be initiated at six hours after administering the dose and should be measured in accordance with standardized procedures.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. The capsules can be utilized up to 30 hours after calibration time and date. Thereafter, discard the capsules in accordance with standard safety procedures. The user should wear waterproof gloves at all times when handling the capsules or container.

Radiation Dosimetry

The estimated absorbed radiation doses to several organs of an average patient (70 kg) from oral administration of the maximum dose of 14.8 MBq (400 μ Ci) of I-123 are shown in Table 4 for thyroid uptakes of 5, 15, and 25%. For comparison at these three values of thyroid uptake, the estimated radiation doses from doses of 3.7 MBq (100 μ Ci) I-131, also used as thyroid imaging agent, are also included.

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

Target Organ	Maximum Thyroid Uptake (%)	Estimated Radiation Absorbed Doses		
		I-123 mGy/14.8 MBq (rads/400 μ Ci)		I-131 mGy/3.7 MBq (rads/100 μ Ci)
		TOC	TOE	
Bladder [†]	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)

*Concentration at Time of Calibration: 97% I-123, 2.9% I-125, 0.1% Te-121
Concentration at Time of Expiry: 87.2% I-123, 12.4% I-125, 0.4% Te-121
Metabolic model in MIRDOSE Report 5 followed for I-123 and I-125
Metabolic model in ICRP 30 followed for Te-121
†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) (NDC 69945-601-10) and 7.4 MBq (200 µCi) (green and white) (NDC 69945-602-20) at time of calibration. Each gelatin capsule contains sucrose as a filler. The capsules are packaged in plastic vials containing one capsule 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 controlled room temperature 20° to 25°C (68° to 77°F).

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.

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Manufactured by: Curium US LLC
Maryland Heights, MO 63043

Made in USA

A601I0

R12/2018

CURIUM™

PRINCIPAL DISPLAY PANEL - A601C0

Sodium Iodide I 123 Capsules

DIAGNOSTIC

For Oral Administration Only

Store at Controlled Room Temperature

20° to 25°C (68° to 77°F)

READ PACKAGE INSERT FOR DIRECTIONS FOR USE

Rx only

WARNING: Radioactive drugs must be handled only by qualified personnel in conformity with regulations of the U.S. Nuclear Regulatory Commission or state regulatory agencies where applicable. Bottle containing drug should be kept in this container or within a heavier shield.

Manufactured by:

Curium US LLC

Maryland Heights, MO 63043

Made in USA

CURIUM™

CAUTION RADIOACTIVE MATERIAL

A601C0

R12/2018

Sodium Iodide I 123 Capsules		Total Act.	MBq/cap	Total Act.	MBq/cap
R12/2018 A601C0	DIAGNOSTIC	(μCi/cap)	(μCi/cap)
	For Oral Administration Only	As of 12 Noon CT		As of 12 Noon CT	
	Store at Controlled Room Temperature	No. of Capsules		No. of Capsules	
	20° to 25°C (68° to 77°F)	Sp. Act.	Carrier Free	Sp. Act.	Carrier Free
	READ PACKAGE INSERT FOR DIRECTIONS FOR USE	Exp. As of 1800 CT		Exp. As of 1800 CT	
	Rx only	Lot		Lot	
WARNING: Radioactive drugs must be handled only by qualified personnel in conformity with regulations of the U.S. Nuclear Regulatory Commission or state regulatory agencies where applicable. Bottle containing drug should be kept in this container or within heavier shield.					
Manufactured by: Curium US LLC Maryland Heights, MO 63043 Made in USA				Sodium Iodide I 123 Capsules Diagnostic	
CURIUM™				CURIUM™	

PRINCIPAL DISPLAY PANEL - A602C0

Sodium Iodide I 123 Capsules

DIAGNOSTIC

For Oral Administration Only

Store at Controlled Room Temperature

20° to 25°C (68° to 77°F)

READ PACKAGE INSERT FOR DIRECTIONS FOR USE

Rx only

WARNING: Radioactive drugs must be handled only by qualified personnel in conformity with regulations of the U.S. Nuclear Regulatory Commission or state regulatory agencies where applicable. Bottle containing drug should be kept in this container or within a heavier shield.

Manufactured by:

Curium US LLC

Maryland Heights, MO 63043

Made in USA

CAUTION RADIOACTIVE MATERIAL

CURIUM™

A602C0 R12/2018

Sodium Iodide I 123 Capsules		Total Act.	MBq/cap	Total Act.	MBq/cap
R12/2018 A602C0	DIAGNOSTIC	(μCi/cap)	(μCi/cap)
	For Oral Administration Only	As of 12 Noon CT		As of 12 Noon CT	
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	20° to 25°C (68° to 77°F)	Sp. Act.	Carrier Free	Sp. Act.	Carrier Free
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Manufactured by: Curium US LLC Maryland Heights, MO 63043 Made in USA				Sodium Iodide I 123 Capsules Diagnostic	
CURIUM™				CURIUM™	

SODIUM IODIDE I 123

sodium iodide i 123 capsule, gelatin coated

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:69945-601

Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	SODIUM IODIDE I-123 (UNII: 29UKX3A616) (IODIDE ION I-123 - UNII:98QPV8670C)	IODIDE ION I-123	100 uCi	
Inactive Ingredients				
	Ingredient Name	Strength		
	SUCROSE (UNII: C151H8M554)			
Product Characteristics				
Color	red, white	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69945-601-10	1 in 1 CAN	11/04/2015	
1		1 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA071909	11/04/2015		

SODIUM IODIDE I 123			
sodium iodide i 123 capsule, gelatin coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69945-602
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	SODIUM IODIDE I-123 (UNII: 29UKX3A616) (IODIDE ION I-123 - UNII:98QPV8670C)	IODIDE ION I-123	200 uCi

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	green, white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69945-602-20	1 in 1 CAN	04/11/2007	
1		1 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071910	04/11/2007	

Labeler - Curium US LLC (079875617)