

DRAIMAGE[®]

SODIUM IODIDE I 131 CAPSULES, USP

DIAGNOSTIC

For Oral Use

DESCRIPTION

Sodium Iodide I 131 Capsules, USP are color-coded capsules containing sodium iodide I 131 for diagnostic use by oral administration. The capsules are available containing 0.33, 0.61, 1.11, 2.03, or 3.7 MBq (9, 16.5, 30, 55, or 100 μ Cl) of sodium iodide I 131 on the calibration date. Each gelatin capsule also contains <0.1 mg of Disodium Edetate Dihydrate and <0.22 mg of Sodium Thiosulfate Pentahydrate absorbed onto approximately 300 mg Sodium Phosphate Dibasic. The specific activity of the I 131 is designated as no-carrier-added.

ACTION

Sodium iodide is rapidly absorbed from the gastrointestinal tract. About 10% - 25% of the administered dose is selectively concentrated from the blood by the normal thyroid gland. The thyroid uses iodine to form thyroid hormones (thyroxine [T4], triiodothyronine [T3]) by iodination of tyrosine residues in thyroglobulin. Iodine is also accumulated but not organified by the stomach mucosa, choroid plexus, lactating breast and salivary glands; the remainder is distributed within the extracellular fluid. Approximately 60% to 90% of the administered dose is excreted in the urine within 24 hours.

INDICATIONS AND USAGE

Sodium Iodide I 131 Capsules, USP are indicated for evaluation of thyroid function by means of the radioiodide thyroid uptake test and for imaging the thyroid gland. It may also be used for the localization of thyroid metastases.

CONTRAINDICATIONS

Because sodium iodide I 131 may cause fetal harm, it is contraindicated in women who are or may become pregnant.

WARNINGS

None.

PRECAUTIONS

General

Goitrogenic foods, many drugs (antitussives, expectorants, glucocorticoids, monovalent anions, sodium nitroprusside, synthetic and natural thyroid preparations, and anti-thyroid medications, iodinated radiographic media, phenylbutazone, salicylates, vitamins, etc.) and certain diseases (nephrosis, impaired renal function, etc.) interfere with the accumulation of radioiodide by the thyroid. Therefore, a careful review of the patient's history, current medication and recent diagnostic tests is required prior to the performance of the thyroid uptake test.

Sodium Iodide I 131 Capsules, USP like other radioactive drugs, must be handled with care. Precautions should be taken to ensure minimum radiation exposure to the patient consistent with proper patient management, and to ensure minimum radiation exposure to occupational workers.

Sodium Iodide I 131 Capsules, USP are radioactive and therefore adequate shielding of the radiopharmaceutical must be maintained.

The expiry time is 30 days from the calibration date which is indicated on the label accompanying the product vial.

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 the carcinogenic or mutagenic potential of Sodium Iodide I 131 Capsules, USP or whether this drug affects fertility in males or females.

Pregnancy

Animal reproduction and teratogenicity studies have not been conducted with Sodium Iodide I 131 Capsules, USP. It is also not known whether Sodium Iodide I 131 Capsules, USP can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women.

Sodium Iodide I 131 Capsules, USP should only be administered to a woman of childbearing capability when appropriate contraceptive measures have been taken or when pregnancy tests are negative. See “CONTRAINDICATIONS”.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Iodine I 131 is excreted in human milk during lactation. Therefore, formula feedings must be substituted for breast feedings.

Pediatric Use

The risk to benefit ratio should be assessed before consideration is given to the use of this product in this age group.

ADVERSE REACTIONS

Adverse effects reported in the literature following the administration of diagnostic radioiodine include nausea, vomiting, and headache.

PHYSICAL CHARACTERISTICS

Iodine 131 decays by beta emission and associated gamma emission with a physical half-life of 8.04 days¹. The principal beta emissions and gamma photons are listed in Table 1.

Table 1
Principal Radiation Emission Data

Radiation	Mean %/ Disintegration	Mean Energy (kev)
Beta-1	2.12	69.4
Beta-3	7.36	96.6
Beta-4	89.30	191.4
Gamma-7	6.05	284.3
Gamma-14	81.20	364.5
Gamma-17	7.26	637.0

External Radiation

The specific gamma ray constant for I 131 is $15.8 \mu\text{Ci} \cdot \text{kg}^{-1} \cdot \text{MBq}^{-1} \cdot \text{h}^{-1}$ (2.27 R/mCi-hr) at 1 cm. The first half value layer is 0.26 cm of lead. A range of values for the relative attenuation of the radiation resulting from the interposition of various thicknesses of lead is shown in Table 2. For example, the use of 4.6 cm of lead will attenuate the radiation emitted by a factor of about 1000.

Table 2
Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.26	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 intervals after calibration are shown in Table 3.

Table 3
Physical Decay Chart
Iodine 131: Half-life 8.04 days

Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
0*	1.00	8	0.50	15	0.274
1	0.917	9	0.460	16	0.252
2	0.842	10	0.422	17	0.231
3	0.772	11	0.387	18	0.212
4	0.708	12	0.355	19	0.194
5	0.650	13	0.326	20	0.178
6	0.596	14	0.299	21	0.164
7	0.547				

*Calibration Time

RADIATION DOSIMETRY

The estimated absorbed radiation doses² to a euthyroid adult patient (70 kg) with different levels of thyroid uptake delivered by the oral administration of a Sodium Iodide I 131 Capsules, USP are shown in Table 4.

Table 4
Absorbed Radiation Doses

Organ	Maximum Thyroid Uptake					
	5%		15%		25%	
	mGy/MBq	rads/mCi	mGy/MBq	rads/mCi	mGy/MBq	rads/mCi
Thyroid	70	260	220	800	350	1300
Stomach Wall	0.46	1.7	0.43	1.6	0.38	1.4
Red Marrow	0.038	0.14	0.054	0.20	0.07	0.26
Liver	0.054	0.2	0.095	0.35	0.13	0.48
Testes	0.023	0.08	0.023	0.09	0.024	0.09
Ovaries	0.038	0.14	0.038	0.14	0.038	0.14
Total Body	0.065	0.24	0.13	0.47	0.19	0.71

DOSAGE AND ADMINISTRATION

The recommended dose range for the average (70 kg) adult patient for thyroid uptake measurement or thyroid imaging is 0.185 - 3.7 megabecquerels (5 - 100 microcuries).

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

DIRECTIONS FOR USE

Sodium Iodide I 131 Capsules, USP are ready for oral administration. Take precautions to minimize radiation exposure by the use of suitable shielding. Waterproof gloves should be worn while handling the radiopharmaceutical.

HOW SUPPLIED

DRAXIMAGE[®] Sodium Iodide I 131 Capsules, USP

Diagnostic

Product No. 0350-071

Color-coded gelatin capsules of sodium iodide I 131 are available containing 0.33, 0.61, 1.11, 2.03, or 3.7 MBq (9, 16.5, 30, 55, or 100 μ Ci) of I 131 at the time of calibration. The capsule color indicates the quantity of I 131 in the capsule and varies with each 5-week production cycle. Sodium Iodide I 131 Capsules, USP are calibrated for the Wednesday following the date of shipment. The specific activity of the I 131 is designated as no-carrier-added. Each gelatin capsule also contains <0.1 mg of Disodium Edetate Dihydrate and <0.22 mg of Sodium Thiosulfate Pentahydrate absorbed onto approximately 300 mg Sodium Phosphate Dibasic.

STORAGE

Sodium Iodide I 131 Capsules, USP should be stored in a dry place at or below room temperature (2°C - 30°C).

EXPIRY

Expiry is 5 weeks from the date of manufacture which is stated on the label accompanying the product vial.

REFERENCES

1. Kocher, David C., "Radioactive Decay Data Tables", DOE/TIC 11026, page 133 (1981).
2. Berman M, Braverman LE, Burke J, De Groot L, McCormack KR, Oddie TH, Rohrer RH, Wellman HN, Smith EM. MIRD Dose Estimate Report No. 5. Summary of Current Radiation Dose Estimates to Humans from ¹²³I, ¹²⁴I, ¹²⁵I, ¹²⁶I, ¹³⁰I, ¹³¹I, and ¹³²I Sodium Iodide. J Nucl Med 1975;16:857-60