HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SODIUM IODIDE I 131 CAPSULES THERAPEUTIC safely and effectively. See full prescribing information for SODIUM IODIDE I 131 CAPSULES THERAPEUTIC.

SODIUM IODIDE I 131 CAPSULES THERAPEUTIC for oral use
Initial U.S. Approval: 1971

----------RECENT MAJOR CHANGES----------
Contraindications (4) 03/2014

----------INDICATIONS AND USAGE----------
Sodium Iodide I 131 Capsules Therapeutic is a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and thyroid carcinomas that take up iodine. Palliative effects may be observed in patients with advanced thyroid malignancy if the metastatic lesions take up iodine. (1)

----------DOSAGE AND ADMINISTRATION----------
Use safe handling measures to minimize inadvertent radiation exposure. (2.1)
Hyperthyroidism
- 148 to 370 megabecquerels (MBq) (4 to 10 millicuries, mCi). Toxic nodular goiter and other situations may require larger doses. (2.2)

Thyroid Carcinoma
- For thyroid carcinoma, 3700 to 5550 MBq (100 to 150 mCi). (2.3)
- For post-operative ablation of normal thyroid tissue: 1850 MBq (50 mCi). (2.3)

Individualize therapy, including dose selection, based upon patient-specific factors detected during the therapeutic planning process. (2.4)

----------DOSAGE FORMS AND STRENGTHS----------
Capsules: available in 18 strengths from 0.75 mCi to 100 mCi at the time of calibration. See full prescribing information for details. (3)

----------CONTRAINDICATIONS----------
- Patients with vomiting and diarrhea (4)
- Treatment of thyroid malignancies shown to have no iodide uptake (4)
- Pregnancy (4)
- Breastfeeding (4)

----------WARNINGS AND PRECAUTIONS----------
- Radiation-induced thyroiditis: may cause or worsen hyperthyroidism; consider pre-treatment with anti-thyroid medications. (5.1)
- Thyroid enlargement, including that due to thyroid stimulating hormone concomitant therapy, may obstruct structures in the neck. Evaluate patients at high risk. (5.2)
- Multiple non-thyroid radiation toxicities have been reported following sodium iodide I-131 therapy, including increased risks for neoplasia, hematopoietic suppression, and fetal or reproductive toxicity. Individualize dosage, verify absence of pregnancy, monitor patients for toxicity, and advise patients on contraceptive use. (5.3, 5.5, 5.6)

----------ADVERSE REACTIONS----------
- Adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of benign disease include sialadenitis, chest pain, tachycardia, iododerma, itching skin, rash, hives, hypothyroidism, hyperthyroidism, thyrotoxic crisis, hypoparathyroidism, and local swelling. (6)
- Adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease include radiation sickness, bone marrow depression, anemia, leucopenia, thrombocytopenia, blood dyscrasia, leukemia, solid cancers, lacrimal gland dysfunction, salivary gland dysfunction, congenital hypothyroidism, and chromosomal abnormalities. (6)

To report SUSPECTED ADVERSE REACTIONS contact Mallinckrodt Inc. at 1-888-744-1414 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

----------DRUG INTERACTIONS----------
Many pharmacologic agents are known to interact with radioiodide. See full prescribing information complete list. (7)

----------USE IN SPECIFIC POPULATIONS----------
- Nursing Mothers: to minimize the absorbed radiation dose to breast tissue, discontinue breastfeeding at least four weeks before sodium iodide I-131 therapy. If administered in the postpartum period, the lactating mother should not breast-feed. (8.3)
- Pediatric Use: safety and effectiveness in pediatric patients have not been established. (8.4)
- Geriatric Use: enhanced evaluation, dose selection and follow-up procedures may be necessary for geriatric patients due to underlying co-morbidities, including renal dysfunction. (8.5)
- Renal Impairment: may increase radiation exposure. (8.6)

See 17 for PATIENT COUNSELING INFORMATION.

Revised 03/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Sodium Iodide I 131 Capsules Therapeutic is indicated for the treatment of hyperthyroidism and thyroid carcinomas that take up iodide. Palliative effects may be observed in patients with advanced thyroid malignancy if the metastatic lesions take up iodide.

2 DOSAGE AND ADMINISTRATION

2.1 Radiation Safety

Sodium iodide I-131 capsules emit radiation and must be handled with safety measures to minimize inadvertent radiation exposure to clinical personnel and patients *[see Warnings and Precautions (5.7)]*.

- Radiopharmaceuticals should be used only by or under the direction of 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.
- Wear waterproof gloves during the entire sodium iodide I-131 capsule handling and administration procedure.
- Maintain adequate shielding during the radiation-emitting life of the product.
- Measure the patient dose using a suitable radioactivity calibration system immediately prior to administration.

2.2 Hyperthyroidism

For hyperthyroidism, the usual sodium iodide I-131 dose range is 148 to 370 MBq (4 to 10 mCi). Higher doses may be necessary for the treatment of toxic nodular goiter and other special situations. Consider discontinuation of anti-thyroid therapy in a severely hyperthyroid patient three to four days before administration of sodium iodide I-131. Evaluate patients for risk of thyroid enlargement and obstruction of structures in the neck *[see Warnings and Precautions (5.1, 5.2)]*.

2.3 Thyroid Carcinoma

For thyroid carcinoma, the usual sodium iodide I-131 therapeutic dose is 3700 to 5550 MBq (100 to 150 mCi). For ablation of post-operative residual thyroid tissue, the usual dose is 1850 MBq (50 mCi).

2.4 Individualization of Therapy

Individualize sodium iodide I-131 therapy, including dose selection, based upon patient-specific factors such as the nature of the underlying condition, co-morbidities, age, estimated thyroid tissue iodine uptake, thyroid size, as well as ability of the patient to comply with the therapeutic regimen and radiation safety procedures. Perform a clinical assessment, including history, physical examination and laboratory testing when preparing patients for sodium iodide I-131 therapy in order to detect conditions which

may alter thyroid iodine uptake and increase the risks of the therapy or diminish its effectiveness. For example, intake of iodine in radiographic contrast may diminish thyroid iodine uptake while low serum chloride or nephrosis may increase thyroid iodine uptake. Obtain a drug history and ascertain whether any medications need to be withheld before the administration of the therapy *[see Drug Interactions (7)]*.

2.5 Radiation Dosimetry

The estimated absorbed radiation doses[1] to an average (70 kg) euthyroid (normal functioning thyroid) patient from an oral dose of iodine-131 in both milligray (mGy) per megabecquerel (MBq) and rad per millicurie (mCi) are shown in Table 1.

Table 1. Absorbed Radiation Doses

Tissue	Thyroid Uptake					
	5%		15%		25%	
	mGy/ MBq	rads/ mCi	mGy/ MBq	rads/ mCi	mGy/ MBq	rads/ mCi
Thyroid	72	266	210	777	360	1300
Stomach Wall	0.45	1.7	0.46	1.7	0.46	1.7
Red Marrow	0.038	0.14	0.054	0.20	0.07	0.26
Liver	0.03	0.11	0.032	0.12	0.035	0.13
Testes	0.029	0.11	0.028	0.10	0.027	0.10
Ovaries	0.044	0.16	0.043	0.16	0.043	0.16
Urinary Bladder	0.58	2.1	0.52	1.9	0.46	1.7
Salivary Glands[2]	0.5	1.85	0.5	1.85	0.5	1.85
Other	0.040	0.15	0.065	0.24	0.090	0.33

3 DOSAGE FORMS AND STRENGTHS

Sodium Iodide I 131 Capsules Therapeutic are opaque white capsules supplied in multiple strengths (Table 2).

Table 2. Capsule Strengths

Strengths Available Total Radioactivity* per Capsule *(* At time of calibration)*	
28 MBq	(0.75 mCi)
74 MBq	(2 mCi)
111 MBq	(3 mCi)
148 MBq	(4 mCi)
185 MBq	(5 mCi)
222 MBq	(6 mCi)
259 MBq	(7 mCi)
296 MBq	(8 mCi)
370 MBq	(10 mCi)
444 MBq	(12 mCi)
555 MBq	(15 mCi)
629 MBq	(17 mCi)
740 MBq	(20 mCi)
1850 MBq	(50 mCi)
3700 MBq	(100 mCi)

4 CONTRAINDICATIONS

Sodium Iodide I 131 Capsules Therapeutic is contraindicated in:

- Patients with vomiting and diarrhea *[see Warnings and Precautions (5.7)]*.
- The treatment of thyroid malignancies shown to have no iodide uptake, which include the majority of medullary and anaplastic carcinomas.
- Pregnancy *[see Warnings and Precautions (5.5)]*.
- Breastfeeding *[see Use in Specific Populations (8.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Radiation-induced Thyroiditis

Sodium iodide I-131 may cause thyroiditis with gland enlargement and release of thyroid hormone, particularly when used to treat hyperthyroidism. The thyroiditis may cause or worsen hyperthyroidism, and may cause thyroid storm. When treating hyperthyroidism, consider pre-treatment with anti-thyroid medication to help deplete the thyroid hormone content within the gland. Discontinue the anti-thyroid medication at least three days before administration of sodium iodide I-131. Consider beta-blocker therapy before administration of sodium iodide I-131 to minimize the risk of hyperthyroidism and thyroid storm.

5.2 Thyroid-stimulating Hormone (TSH) and Thyroid Enlargement

Enhanced TSH secretion, e.g., following discontinuation of anti-thyroid medications, or the administration of TSH to enhance sodium iodide I-131 uptake, may cause thyroid enlargement and obstructive complications of the trachea, esophagus, or blood vessels in the neck. Evaluate patients at high risk of obstructive complications before preparative treatments known to cause thyroid enlargement.

5.3 Radiation-induced Toxicities

Radiation-induced toxicities, including dose-dependent fatalities, have been reported following sodium iodide I-131 therapy. Post-marketing reports have identified an increased risk for neoplasia, as well as risks for hematopoietic suppression. Salivary and lacrimal gland toxicity is relatively common and may manifest as conjunctivitis, xerophthalmia, epiphora, sialadenitis and xerostomia *[see Adverse Reactions (6)]*.

5.4 Hypersensitivity Reactions

Hypersensitivity reactions, including rash and hives have been reported following administration of sodium iodide I-131. Sodium iodide I-131 capsules may contain sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes. 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. During the pre-therapy assessment, question patients about a history of hypersensitivity to sulfite *[see Adverse Reactions (6)]*.

5.5 Fetal Risk

Transplacental passage of sodium iodide I-131 can cause severe and possibly irreversible hypothyroidism in neonates *[see Contraindications (4)]*.

Females and Males of Childbearing Potential

When planning sodium iodide I-131 therapy for women of childbearing potential, obtain a pregnancy test and verify the absence of a pregnancy before initiating treatment. Advise women and men of childbearing potential to use two effective methods of contraception to avoid pregnancy for at least six months after sodium iodide I-131 administration. Advise patients of the potential need to use two effective methods of contraception to avoid pregnancy for an even longer period of time (e.g., one year) if additional sodium iodide I-131 therapy or radionuclide imaging is anticipated.

5.6 Transient Infertility

Transient, dose-related impairment of testicular function has been reported after sodium iodide I-131 therapy. Consider sperm banking for men who are anticipated to receive a high cumulative sodium iodide I-131 dose (e.g., greater than 14 GBq).

In females, transient ovarian failure has been observed after sodium iodide I-131 therapy.

5.7 Radiation Exposure Risk to Other Individuals

Unwanted radiation exposure can occur from handling and administration of radiopharmaceuticals or from contaminated waste products, including urine and feces. Follow safe administration instructions to minimize unnecessary radiation exposure to patients and health care workers *[see Dosage and Administration (2.1)]*. Instruct patients on how to reduce unnecessary radiation exposure to others, especially family members following treatment.

Review the most recent professional society guidelines and publications that describe the procedures for the safe use of sodium iodide I-131 therapy to minimize radiation toxicity risks to patients, radiation exposure risks to other individuals, and environmental radiation contamination risks.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below and elsewhere in labeling:

- Radiation-induced Thyroiditis *[see Warnings and Precautions (5.1)]*
- Thyroid-stimulating Hormone and Thyroid Enlargement *[see Warnings and Precautions (5.2)]*
- Radiation-induced Toxicities *[see Warnings and Precautions (5.3)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.4)]*
- Fetal Risk *[see Warnings and Precautions (5.5)]*
- Transient Infertility *[see Warnings and Precautions (5.6)]*
- Radiation Exposure to Other Individuals *[see Warnings and Precautions (5.7)]*

Radiation-related adverse reactions are a function of the dose level received by the patient.

The following adverse reactions have been reported with doses of sodium iodide I-131 used in the treatment of benign disease, such as hyperthyroidism:

- *Gastrointestinal disorders:* sialadenitis
- *Cardiac disorders:* chest pain and tachycardia
- *Skin and subcutaneous tissue disorders:* iododerma, itching skin, rash, and hives
- *Endocrine disorders:* hypothyroidism, hyperthyroidism, thyrotoxic crisis, hypoparathyroidism
- *General disorders and administration site conditions:* local swelling

The following adverse reactions have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease:

- *Blood and lymphatic system disorders including fatalities:* radiation sickness, bone marrow depression, anemia, leucopenia, thrombocytopenia, and blood dyscrasia
- *Neoplasms benign, malignant and unspecified (including cysts and polyps):* leukemia and solid cancers
- *Eye disorders:* lacrimal gland dysfunction
- *Gastrointestinal disorders:* salivary gland dysfunction, nausea, vomiting
- *Congenital, familial and genetic disorders:* congenital hypothyroidism and chromosomal abnormalities

Adverse reactions that occur after treatment of benign disease may also occur after treatment of malignant disease. Tenderness, pain on swallowing, sore throat, and cough have been reported, generally around the third day after sodium iodide I-131 administration.

7 DRUG INTERACTIONS

Many pharmacologic agents interact with sodium iodide I-131. These agents may affect the iodide protein binding and alter the iodide pharmacokinetics and pharmacodynamics.

Table 3. Drug Interactions

Substance	Average Duration of Effect
Anti-thyroid drugs	
e.g., carbimazole, propylthiouracil	5 days
Natural or synthetic thyroid hormone	
e.g., thyroxine	4 weeks
tri-iodothyronine	2 weeks
Iodine-containing medications	
e.g., amiodarone	4 weeks
expectorants, vitamins	2 weeks
Topical iodide	1-9 months
X-ray contrast agents	
iodine-containing agents	Up to 1 year
Other drugs	
anticoagulants, antihistamines	1 week
corticosteroids, sulfonamides	1 week
tolbutamide, perchlorate	1 week
phenylbutazone	1-2 weeks
lithium	4 weeks

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Pregnancy Category X *[see Warnings and Precautions (5.5)]*.

8.3 Nursing Mothers
Sodium iodide I-131 is excreted into human milk and may reach concentrations equal to or greater than concentrations in maternal plasma. To minimize the absorbed radiation dose to the breast tissue, breastfeeding and breast-pumping should be discontinued for at least four weeks before administration of sodium iodide I-131. Sodium iodide I-131 is contraindicated in pregnancy; if sodium iodide I-131 is administered in the postpartum period, the lactating mother should not breast-feed the infant. Breastfeeding may resume with the birth of another child, if the mother does not receive sodium iodide I-131 during that postpartum period.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients have not been established. Published reports suggest that the thyroid gland of pediatric patients is more sensitive to the effects of sodium iodide I-131; however, it is unknown if the I-131 dose-response relationship is similar to that of adults. When considering the use of sodium iodide I-131 in pediatric patients, the risks, particularly carcinogenic risks, and benefits of sodium iodide I-131 must be carefully weighed against those of other possible treatments.

8.5 Geriatric Use
Because elderly patients are more likely to have decreased renal function and co-morbid conditions, enhanced evaluation, dose-selection consideration and follow-up may be necessary for elderly patients receiving sodium iodide I-131 therapy, compared to younger patients *[see Use in Specific Populations (8.6)]*.

When treating hyperthyroidism in geriatric patients at risk of developing cardiac complications, pre-treatment and post-treatment with anti-thyroid drugs and/or beta-blockers may help minimize the risk of excessive post-treatment hyperthyroidism due to radiation-induced thyroiditis *[see Warnings and Precautions (5.1)]*.

8.6 Renal Impairment
Sodium iodide I-131 is eliminated predominantly through renal clearance. Patients with renal impairment are subject to decreased excretion of sodium iodide I-131 and increased radiation exposure. Evaluate renal function for therapeutic planning *[see Dosage and Administration (2.4)]*. Sodium iodide I-131 is dialyzable. Hemodialysis can be used to reduce total body radiation exposure.

10 OVERDOSAGE
In case of exposure to a radioactive dose of sodium iodide I-131 exceeding the intended therapeutic dose provide general supportive care, monitor for bone marrow and thyroid suppression and consider administering a thyroid blocking agent such as potassium iodide (KI) or perchlorate promptly within 4 to 6 hours after the exposure. Thyroid

blockade may reduce radiation exposure of thyroid tissue but would not prevent radiation injury to the rest of the body. Assess the benefit of administering a blocking agent against the risk of failure of sodium iodide I-131 therapy.

11 DESCRIPTION

Sodium Iodide I 131 (Na I-131) Capsules Therapeutic is supplied for oral administration in opaque white gelatin capsules. The capsules are available in strengths ranging from 28 to 3700 MBq (0.75 to 100 mCi) iodine-131 at the time of calibration. Sodium iodide I-131 capsules are packaged in shielded, plastic vials containing one capsule per vial.

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

11.1 Physical Characteristics

Iodine-131 decays by beta emission and associated gamma emission with a physical half-life of 8.02 days[3]. The principal beta emissions and gamma photons are listed in Table 4.

Table 4. Principal Radiation Emission Data

Radiation	Mean Percent Per Disintegration	Energy (keV)
Beta-1	2.10	69.4 Avg.
Beta-3	7.27	96.6 Avg.
Beta-4	89.9	191.6 Avg.
Gamma-7	6.14	284.3
Gamma-14	81.7	364.5
Gamma-17	7.17	637.0

11.2 External Radiation

The specific gamma ray constant for iodine-131 is 2.20 R/hr-mCi at 1 cm. The first half-value thickness of lead (Pb) for iodine-131 is 0.27 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 5. For example, the use of 4.5 cm of Pb will decrease the external radiation exposure by a factor of about 1,000.

Table 5. Radiation Attenuation by Lead Shielding[4]

Shield Thickness (Pb), cm	Coefficient of Attenuation
0.27	0.5
0.99	10^{-1}
2.6	10^{-2}
4.5	10^{-3}

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 6.

Table 6. Physical Decay Chart
Iodine-131: Half-Life 8.02 Days

Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	11	0.387	22	0.149
1	0.917	12	0.355	23	0.137
2	0.841	13	0.325	24	0.126
3	0.772	14	0.298	25	0.115
4	0.708	15	0.274	26	0.106
5	0.649	16	0.251	27	0.097
6	0.595	17	0.230	28	0.089
7	0.546	18	0.211	29	0.082
8	0.501	19	0.194	30	0.075
9	0.459	20	0.178		
10	0.421	21	0.163		

*Calibration Day

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Taken orally, sodium iodide I-131 is rapidly absorbed and distributed within the extracellular fluid of the body. The iodide is concentrated in the thyroid via the sodium/iodide symporter, and subsequently oxidized to iodine. The destruction of thyroidal tissue is achieved by the beta emission of sodium iodide I-131.

12.2 Pharmacodynamics

The therapeutic effects of sodium iodide I-131 are a result of the ionizing radiation absorbed by the thyroidal tissue. Tissue damage is the result of direct insult to molecules by ionization and excitation and the consequent dissociation of those molecules. About 90% of local irradiation from sodium iodide I-131 is the result of beta radiation and 10% is the result of gamma radiation.

12.3 Pharmacokinetics

After oral administration, sodium iodide I-131 is absorbed rapidly from the upper gastrointestinal tract (90% in 60 minutes). The pharmacokinetics follow that of unlabelled iodide. After entering the blood stream, the iodide is distributed into the extra thyroidal compartment. From here it is predominantly taken up by the thyroid or excreted renally. In the thyroid, the trapped iodide is oxidized to iodine and organified. The sodium/iodide symporter (NIS) is responsible for the concentration of iodide in the thyroid. This active transport process concentrates iodide 20 to 40 times the plasma concentration under normal circumstances, and this may increase tenfold in the hyperthyroid state. NIS also mediates active iodide transport in other tissues, including salivary glands, nasolacrimal duct, lacrimal sac, gastric mucosa, lactating mammary gland, and the choroid plexus. The non-thyroidal iodide transporting tissues do not have the ability to organify accumulated iodide.

Depending on renal and thyroid gland function, urinary excretion is 37 to 75% of the administered dose, fecal excretion is about 10%, and excretion in sweat is almost negligible.

15 REFERENCES

1 International Commission on Radiological Protection. Radiation Dose to Patients from Radiopharmaceuticals. ICRP Publication 53, Pergamon Press, New York, NY, 1988.

2 L. Johansson, S. Leide-Svegborn, S. Matteson, B. Nosslin. Biokinetics of Iodide in Man: Refinement of Current ICRP Dosimetry Models. Cancer Biotherapy & Radiopharmaceuticals, 18(3): 445-450, 2003.

3 Stabin MG, da Luz CQPL. Decay Data for Internal and External Dose Assessment, Health Phys. 83(4):471-475, 2002.

4 Smith David S., Stabin, Michael G. Exposure Rate Constants and Lead Shielding Values for Over 1,100 Radionuclides, Health Physics. 102(3):271-291, March 2012.

16 HOW SUPPLIED/STORAGE AND HANDLING

Sodium Iodide I 131 Capsules Therapeutic is supplied in a shielded, plastic vial containing one opaque white gelatin capsule per vial. The capsules are available in strengths ranging from 28 to 3700 MBq (0.75 to 100 mCi) iodine-131 at the time of calibration. 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. Do not use the product after the expiration date.

Sodium Iodide I 131 Capsules for Therapeutic Use	
NDC	**mCi Capsule**
0019-9452-75	0.75
0019-9452-02	2
0019-9452-03	3
0019-9452-04	4
0019-9452-05	5
0019-9452-06	6
0019-9452-07	7
0019-9452-08	8
0019-9452-10	10
0019-9452-12	12
0019-9452-15	15
0019-9452-17	17
0019-9452-20	20
0019-9452-50	50
0019-9452-00	100

Storage

Store at a controlled room temperature of 20° to 25°C (68° to 77°F). Storage and disposal of Sodium Iodide I 131 Capsules Therapeutic 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 10 CFR 35.300, and to persons who hold an equivalent license issued by an Agreement State.

17 PATIENT COUNSELING INFORMATION

Review the most recent professional society guidelines and publications that describe important components of the patient counseling process.

- Discuss the measures to minimize inadvertent radiation exposure to the patient, members of the patient's household, the public, and the environment.
- Advise females and males of reproductive potential of the need to use two effective methods of contraception to avoid pregnancy for at least 6 months after I-131 administration due to fetal risk. Advise patients of the potential need to use two effective methods of contraception to avoid pregnancy for an even longer period of time (e.g., one year) if additional sodium iodide I-131 therapy and further radionuclide imaging is anticipated.
- Advise patients of the possibility of transient infertility and possible use of sperm banking for males of reproductive potential.

- Among lactating females, discuss the need to discontinue breastfeeding and pumping at least four weeks before administration of sodium iodide I-131. If sodium iodide I-131 is administered in the postpartum period, advise the lactating mother to not breastfeed her infant.

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Mallinckrodt Inc.
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