# YOUR ONLY U.S. PRODUCED SOURCE OF FDA APPROVED SODIUM IODIDE I-131

SODIUM IODIDE I-131 Kit for the preparation of Sodium Iodide I-131 Capsules and Solution USP, Therapeutic – Oral
INDICATIONS AND USEAGE: Sodium iodide I-131 is a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and selected cases of carcinoma of the thyroid.

**THE ONE AND ONLY FDA APPROVED SODIUM IODIDE I-131 DRUG PRODUCT MANUFACTURED IN THE UNITED STATES.**

**International Isotopes Inc. takes pride in** providing you with exceptional and responsive customer service throughout the ordering process. We work to accommodate your varied order needs and delivery schedules. Our goal is to reliably provide you with high quality GMP product on a schedule to best meet your needs.

**Flexible Ordering!** Our Sodium Iodide I-131 kits offer you a variety of vial sizes and a range of activities.[1]


## Get One Day Shipping, No Contract Required

For complete ordering information, please contact International Isotopes customer service by calling (208) 524-5300 or e-mail: iodineinfo@intisoid.com


**International Isotopes Inc.**
4137 Commerce Circle Idaho Falls, ID 83401
Toll Free: (800) 699-3108
**www.intisoid.com**


1 The product is offered in a fixed concentration of 1000 mCi/mL. In addition to the bulk solution of SODIUM IODIDE I-131 each order may include at least one carton of capsules which contains two blister packs with five empty Size 1 capsules and five dibasic sodium phosphate filled Size 2 capsules per blister (a total of 10 empty & 10 filled capsules). Larger order sizes may contain an increased number of capsule packages.

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

INDICATIONS AND USAGE:
Sodium Iodide I-131 is a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and selected cases of carcinoma of the thyroid. (1)

DOSAGE AND ADMINISTRATION:
- The concentrated sodium iodide I 131 solution provided must be diluted. (2.2)
- See Full Prescribing Information for important administration instructions and dilution and preparation instructions for sodium iodide I 131 capsules or oral solution. (2.2, 2.4)
- The recommended dose is based on the thyroid gland uptake as well as the size of the gland:
- Treatment of Hyperthyroidism: Recommended dosage is 148 to 370 megabecquerels (MBq) [4 to 10 millicuries (mCi). (2.3)
- Treatment of Thyroid Carcinoma: Recommended dosage is 1,110 to 33,700 MBq (30 to 100 mCi). (2.3)

DOSAGE FORMS AND STRENGTHS:
Vials: Sodium Iodide I-131 solution (with a radioconcentration pF 37,000 MBq/mL (1000 mCi/mL) at the time of calibration) for the preparation of sodium iodide I-131 capsules, therapeutic or sodium iodide I-131 solution, therapeutic. (3)

CONTRAINDICATIONS:
Patients with vomiting and diarrhea. (4)
Pregnancy. (4)
Lactation. (4)
Patients receiving concurrent anti-thyroid therapy.

WARNINGS AND PRECAUTIONS
- Radiation-induced thyroiditis may cause or worsen hyperthyroidism. Consider pre-treatment with anti-thyroid medications. (5.1)
- Multiple non-thyroid radiation toxicities, including hematopoietic suppression: Individualize dose and monitor for toxicity. (5.2)
- Fetal toxicity: May cause severe and irreversible hypothyroidism in the neonate. Verify absence of pregnancy before administering the product. (5.4, 8.1, 8.3)
- Radiation exposure to breast tissue with lactation: Sodium iodide I 131 concentrates in the breast of lactating women. Discontinue lactation 6 weeks prior to therapy. (5.5, 8.2)

ADVERSE REACTIONS:
Common adverse reactions reported with therapeutic doses of sodium iodide I 131 include local swelling, radiation sickness, sialadenitis, salivary gland dysfunction, bone marrow depression, lacrimal gland dysfunction, hypothyroidism, hyperthyroidism, thyrotoxic crisis, acute leukemia, solid cancer. (6)
To report SUSPECTED ADVERSE REACTIONS, contact International Isotopes Inc. at 1-800-699-3108 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

HYPERSENSITIVITY REACTIONS:
Hypersensitivity reactions including anaphylaxis may occur in patients who receive sodium iodide I 131. Although iodide is not considered an allergen, hypersensitivity reactions may occur in relation with excipients or chemical component of the capsule, such as sodium thiosulfate. Obtain and document an allergy history, particularly a sulfite allergy. Emergency resuscitation equipment and personnel should be immediately available. (5.3)

HOUSEHOLD CONTACTS:
Household Contacts Instruct patients to follow radiation safety precautions after receiving Sodium Iodide I-131 to minimize the radiation contamination of other persons or the environment. Patients should avoid close contact with others, especially pregnant women and children, and take care to avoid contamination of other persons or the environment with body fluids. (5.7)

PATIENTS AND HEALTHCARE PROVIDERS:
Patients and Healthcare Providers Sodium Iodide I-131 contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Follow safe handling and administration to minimize radiation exposure to the patient and healthcare providers. (5.7)

DRUG INTERACTIONS & RISK OF DECREASED EFFECTIVENESS:
Many drugs and iodine-containing foods interfere with the accumulation of radioiodide by the thyroid. Instruct patients to maintain a low-iodide diet (2 weeks) and discontinue anti-thyroid therapy (3 days) before administration. (5.8, 7)

USE IN SPECIFIC POPULATIONS:
- Females and Males of Reproductive Potential: May impair fertility in females and males. (5.6, 8.3)
- Geriatric Use: Dose selection may be necessary for geriatric patients due to possible decreased renal function. (8.5)
- Renal Impairment: May increase radiation exposure. (5.2, 8.6)

| "V" Vial Size (mL) | Minimum (mCi) | Maximum (mCi) |
|---|---|---|
| 1 | 400 | 750 |
| 2 | 400 | 1500 |
| 3 | 400 | 2250 |