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 l 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.

----------DRUG INTERACTIONS----------

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)