SODIUM IODIDE I-131 - sodium iodide i-131 solution
International Isotopes Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

SODIUM IODIDE I-131 SOLUTION(for the preparation of sodium iodide I-131 solution or sodium iodide I-131 capsules), therapeutic, for oral use.

Initial U.S. Approval: 1971

RECENT MAJOR CHANGES

Dosage and Administration (2)	10/2021
Contraindications (4)	10/2021
Warnings and Precautions (5)	10/2021

INDICATIONS AND USAGE

Sodium Iodide I-131 Solution 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 MBq to 370 MBq (4 mCi to 10 mCi). (2.3)
  - Treatment of Thyroid Carcinoma: Recommended dosage is 1,110 MBq to 3,700 MBq (30 mCi to 100 mCi). (2.3)

DOSAGE FORMS AND STRENGTHS

Vials: Sodium Iodide I-131 Solution (with a radioconcentration of 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)
- Patients with thyroid malignancies shown to have no iodide uptake. (4)
- Patients receiving concurrent anti-thyroid therapy. (4)
- Pregnancy. (4)
- Lactation. (4)

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)
- Embryo-Fetal toxicity: May cause severe and irreversible hypothyroidism in the neonate. Verify pregnancy status in females of reproductive potential prior to initiating treatment. Females and males of reproductive potential should use effective contraception. (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 breast feeding at least 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. (6)

To report SUSPECTED ADVERSE REACTIONS, contact International Isotopes Inc. at 1-800-699-3108 or FDA at 1-888-INFO-FDA (1-888-463-6332) or https://www.accessdata.fda.gov/scripts/medwatch

DRUG INTERACTIONS

Many pharmacologic agents are known to interact with radioiodide. See Full Prescribing Information complete list. (5.8, 7)

USE IN SPECIFIC POPULATIONS

- Pregnancy. (4)
- Lactation. (4)
- Females and Males of Reproductive Potential: May impair fertility in females and males. (5.6, 8.3)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 09/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

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