PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC

(Sodium Iodide I 131 Capsules, USP for oral use)
Capsule, 3.7 MBq

DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC

(Sodium Iodide I 131 Solution, USP for oral use)
Solution, 74 MBq to 925 MBq / vial

Diagnostic Radiopharmaceutical Agent

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RECENT MAJOR LABEL CHANGES

7 WARNING AND PRECAUTIONS	6/2023
7 WARNINGS AND PRECAUTIONS, 7.1.1 Pregnant Women	6/2023
7 WARNINGS AND PRECAUTIONS, 7.1.2 Breastfeeding	6/2023
7 WARNINGS AND PRECAUTIONS, 7.1.4 Geriatrics	6/2023

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC (Sodium Iodide I 131 Capsule, USP) and DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC (Sodium Iodide I 131 Solution, USP) [DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC] are indicated for:

- Assessment of thyroid function using radioactive iodine (RAI) uptake test;
- Imaging the thyroid (scintigraphy);
- Localization of thyroid metastases.

1.1 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (> 65 years of age): No data are available to Health Canada. There is no evidence from clinical studies and experience to suggest that use in the geriatric population is associated with differences in safety or effectiveness (see 7.1 Special Populations).

2 CONTRAINDICATIONS

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC are contraindicated in pregnancy (see 7 WARNINGS AND PRECAUTIONS) and in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.

Although iodide is not considered an allergen, hypersensitivity reactions may occur in relation with excipients or chemical component of the capsule (in the case of the capsule dosage form), such as sodium thiosulfate (see 8 ADVERSE REACTIONS).

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC should be used only by those health professionals who are appropriately qualified in the use of radioactive prescribed substances in or on humans (see 12 SPECIAL HANDLING INSTRUCTIONS).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC is contraindicated in pregnancy. Obtain a pregnancy test in females of reproductive potential and verify the absence of pregnancy within 24 hours prior to administration of treatment (see 7 WARNINGS AND PRECAUTIONS).

4.2 Recommended Dose and Dosage Adjustment

Administer DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC orally prior to scanning. The recommended dose of DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC for an adult patient is the following:

- **Thyroid Function:** 0.185 MBq to 1.1 MBq (5 microCi to 30 microCi) administered orally. Administer 24 hours before uptake measurement.
- **Thyroid Imaging (Scintigraphy):** 1.85 MBq to 3.7 MBq (50 microCi to 100 microCi). Administer 16 to 24 hours before imaging.
- **Localization of Thyroid Metastases:** 74 MBq to 185 MBq (2 mCi to 5 mCi) in the solution form.

For DRAXIMAGE SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC, consult the color-coded decay calendar that is updated January of every year to determine which colored capsule(s) correspond to the prescribed dose: https://www.draximage.com/products/Canada/draximage-I-131-diagnostic-capsules or calculate the correct dose from the date and time of calibration provided on the container label.

4.4 Administration

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC are ready for oral administration to patients. Prior to DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC administration:

- Obtain a pregnancy test in females of reproductive potential to verify the absence of pregnancy (see 2 CONTRAINDICATIONS and 7.1.1 Pregnant Women).
- Instruct patients to fast at least 2 hours before and 2 hours after administration to ensure absorption.
- Instruct patients to hydrate before and after administration of sodium iodide I 131 and to void frequently to enhance urinary elimination of the radioiodide that is not absorbed by the thyroid gland (see 7 WARNINGS AND PRECAUTIONS).
- Instruct patients to maintain a low-iodide diet two weeks prior to radioiodide administration and continue for several days during the uptake or imaging process (see 7 WARNINGS AND PRECAUTIONS and 9 DRUG INTERACTIONS).

4.7 Instructions for Preparation and Use

Drug Handling

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC are radioactive drugs and should be handled with appropriate safety measures to minize radiation exposure to the patient and healthcare worker (see 7 WARNINGS AND PRECAUTIONS).

- Use waterproof gloves during the entire handling and administration procedure.
- Maintain adequate shielding during the life of the product.
- Open the vial in a well ventilated hood to avoid exposure to trace levels of volatile I-131 which may be present.
- Measure patient dose by a suitable radioactivity calibration system immediately prior to administration.

4.8 Radiation Dosimetry

- The biokinetic modeling and radiation dose distributions associated with thyroid uptake of iodide I 131 depend on dietary intake of stable iodide and presume normal production of thyroid hormone. Table 1 shows a range of uptake percentages in an average adult (73.7 kg reference model).
- For a thyroid blocked from iodide uptake in the production of hormones, the effective half-life of iodide I 131 is approximately 1.4 hours; for “low” to “high” uptake, the effective half-life of I 131 ranges from approximately 80 to 90 hours.

Table 1. Absorbed dose per unit activity sodium iodide I 131 administered orally (mGy/MBq) in adult (73.7 kg reference model)

Organ	Thyroid uptake of I 131 (% administered activity A_0) 24 h after oral administration			
	Blocked thyroid (0% A_0)	Low uptake (16% A_0)	Medium uptake (26% A_0)	High uptake (36% A_0)
Adrenals	0.044	0.051	0.055	0.059
Bone surfaces	0.03	0.089	0.12	0.16
Brain	0.021	0.093	0.13	0.17
Breast	0.02	0.038	0.048	0.058
Gallbladder wall	0.037	0.043	0.046	0.049
Gastrointestinal tract				
Esophagus	0.024	0.1	0.14	0.19
Stomach wall	0.87	0.77	0.71	0.66
Small intestine wall	0.035	0.033	0.032	0.032
Colon wall	0.14	0.14	0.14	0.14
(Upper large intestine wall)	0.12	0.12	0.12	0.12
(Lower large intestine wall)	0.17	0.17	0.17	0.16
Heart wall	0.062	0.089	0.1	0.12
Kidneys	0.27	0.27	0.27	0.27
Liver	0.05	0.093	0.12	0.14

Lungs	0.053	0.1	0.13	0.15
Muscles	0.026	0.084	0.12	0.15
Ovaries	0.038	0.037	0.036	0.035
Pancreas	0.06	0.064	0.066	0.068
Red marrow	0.031	0.072	0.095	0.12
Salivary glands	0.27	0.22	0.19	0.16
Skin	0.019	0.043	0.057	0.071
Spleen	0.064	0.069	0.072	0.075
Testes	0.025	0.024	0.023	0.22
Thymus	0.024	0.1	0.14	0.19
Thyroid	2.2	280	430	580
Urinary bladder wall	0.54	0.45	0.39	0.34
Uterus	0.045	0.042	0.04	0.038
Remaining organs	0.029	0.084	0.11	0.15
Effective dose per administered activity (mSv/MBq)	0.28	14	22	29

5 OVERDOSAGE

In the event of an overdosage of DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC, monitor for thyroid suppression and consider administering a thyroid blocking agent (e.g. potassium iodide (KI) or perchlorate). Promote frequent voiding and encourage patients to maintain hydration to minimize radiation exposure.

In case of any reportable radiation overdose, please contact the Canadian Nuclear Safety Commission

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Oral	Capsules 3.7 MBq (100 microCi) / capsule Sodium Iodide I 131, USP	Each gelatin capsule also contains: < 0.1 mg of Disodium Edetate Dihydrate, < 0.22 mg of Sodium Thiosulfate Pentahydrate absorbed onto approximately 300 mg Sodium Phosphate Dibasic.

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC are color-coded capsules containing sodium iodide I-131 for diagnostic use by oral administration. Each capsule contains 3.7 MBq (100 microCi) of I-131 at time of calibration. Half of each capsule is white, while the other half is either pink, yellow, orange, grey or green according to the manufactured lot. The capsule will yield 2.03, 1.11, 0.61, or 0.33 MBq (55, 30, 16.5, or 9 microCi) according to

the color-coded decay calendar which assigns a color and capsule activity for each week of the year. https://www.draximage.com/products/Canada/draximage-I-131-diagnostic-capsules. The specific activity of sodium iodine I-131 is designated as carrier-free.

Table 2 below displays the (5) weeks activity of the capsules starting from the calibration day.

Table 2. Weekly Activity (MBq and microCi) of Each Capsule Stating from the Calibration Day

Week	Activity (MBq)	Activity (microCi)
1	3.70	100
2	2.03	54.9
3	1.11	30
4	0.61	16.5
5	0.33	8.9

DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients
Oral	Solution 74 MBq to 925 MBq (2 mCi to 25 mCi) / vial Sodium Iodide I 131, USP	Each mL of aqueous solution contains: < 2 mg of Disodium Edetate Dihydrate, < 4.4 mg of Sodium Thiosulfate Pentahydrate, < 40 mg of Disodium Phosphate Anhydrous.

DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC is an aqueous solution containing sodium iodide I-131 for diagnostic use by oral administration. The solution is available from 74 MBq to 925 MBq (2 mCi to 25 mCi) of I-131 at the calibration date. The pH of the solution is between 7.5 and 9. The specific activity of sodium iodine I-131 is designated as carrier-free.

6.1 Physical Characteristics

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

Table 3. Principal Radiation Emission Data from Decay of Sodium Iodide I 131

Radiation	Mean % per Disintegration	Mean Energy (keV)
Beta-1	2.1	69.4
Beta-3	7.2	96.6
Beta-4	89.4	191.6
Gamma-7	6.1	284.3

Gamma-14	81.2	364.5
Gamma-18	7.1	637.0

6.2 External Radiation

The specific gamma-ray constant for iodide I 131 is 4.26 x 10^{-13} C•m^2•kg^{-1}•MBq^{-1}•s^{-1} (2.2 R•cm^2/mCi•hr). The first half-value thickness of lead (Pb) for iodide I 131 is 0.27 cm. A range of values for the relative attenuation of the radiation emitted by iodide I 131 that results from the interposition of various thicknesses of Pb is shown in Table 4. For example, the use of 2.59 cm of Pb will decrease the external radiation exposure by a factor of about 1,000.

Table 4. Radiation Attenuation of Iodide I 131 by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.27	0.5
0.56	0.25
0.99	10^{-1}
2.59	10^{-2}
4.53	10^{-3}

To correct for physical decay of iodide I 131, the fractions that remain at selected intervals after the time of calibration are shown in Table 5.

Table 5. Physical Decay Chart Iodine I 131: Half-life 8.02 Days

Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	8	0.503	16	0.253	24	0.127
1	0.918	9	0.461	17	0.232	25	0.116
2	0.842	10	0.423	18	0.213	26	0.107
3	0.773	11	0.388	19	0.195	27	0.098
4	0.709	12	0.356	20	0.179	28	0.090
5	0.651	13	0.327	21	0.164	29	0.083
6	0.597	14	0.300	22	0.151	30	0.076
7	0.548	15	0.275	23	0.138		

* Calibration Time

7 WARNINGS AND PRECAUTIONS

Please see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

General

The product should be administered under the supervision of a health professional who is experienced in the use of radiopharmaceuticals. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily

available.

The radiopharmaceutical product may be received, used and administered only by authorized persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of local competent official organizations.

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to occupational workers.

Immune

Sensitivity

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, particularily a sulfite allergy. Emergency resuscitation equipment and personnel should be immediately available (see 8 ADVERSE REACTIONS).

Monitoring and Laboratory Tests

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC are contraindicated in pregnancy because of the risk of fetal hypothyroidism. Obtain a pregnancy test in females of reproductive potential and verify the absence of pregnancy within 24 hours prior to administration of DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC (see 7.1 Special Populations).

Radiation Contamination

As in the use of any radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to occupational workers.

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC 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.

Reproductive Health: Female and Male Potential

- **Teratogenic Risk**

  DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC is contraindicated in pregnancy because sodium iodide I 131 crosses the placenta and fetal exposure can lead to neonatal hypothyroidism. Multiple reports in the published literature describe hypothyroidism in the neonates following in utero exposure to sodium iodide I 131. Some cases of neonatal hypothyroidism were severe and irreversible. Obtain a pregancy

test in females of reproductive potential and verify the absence of pregnancy before administering DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC (see 4 DOSAGE AND ADMINISTRATION and 7.1 Special Populations).

Risk of Radioactive Uptake Measurement and Imaging Misinterpretation

The recent intake of stable iodine in any form, or the use of thyroid or anti-thyroid drugs will affect the uptake of sodium iodide I 131. Question the patient carefully regarding their exposure to these drugs or procedures involving radiographic contrast media. (see 9 DRUG INTERACTIONS).

7.1 Special Populations

7.1.1 Pregnant Women:

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC is contraindicated in pregancy because fetal exposure can lead to neonatal hypothyroidism, which in some cases is severe and irreversible (see 7 WARNINGS AND PRECAUTIONS). Data from the published literature describe reports of neonatal thyroid abnormalities after fetal exposure; including agenesis of the thyroid and hypothyroidism (see Fetal/Neonatal Adverse Reactions). No animal reproductive studies have been conducted.

Fetal/Neonatal Adverse Reactions

A fetus exposed to sodium iodide I 131 can develop neonatal hypothyroidism. Delay in diagnosis of neonatal hypothyroidism after exposure to sodium iodide I 131 in utero can result in severe sequela such as cognitive impairment and delayed bone age. Monitor thyroid function in any infant born after in utero exposure to sodium iodide I 131.

Sodium iodide I 131 crosses the placenta and the fetal thyroid begins to concentrate iodide during the 10^{th} to 12^{th} week of gestation. In literature reports of maternal exposures to sodium iodide I 131 at doses of 333 MBq to 8,325 MBq (9 mCi to 225 mCi) during 4 to 26 weeks gestational age, the most common adverse outcomes were hypothyroid infants and children.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability, should be performed during the first ten days following the onset of menses or after ensuring the woman is not pregnant. The benefit of using a diagnostic radiopharmaceutical should be weighed against the possible risk to an embryo or a fetus.

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC should only be administered to a woman of childbearing capacity when appropriate contraceptive measures have been taken or when pregnancy tests are negative (see 2 CONTRAINDICATIONS).

7.1.2 Breastfeeding

Advise women to discontinue breastfeeding after administration of SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC. Infant exposure to sodium iodide I 131 via breast milk is expected and may lead to hypothyroidism in the infant because sodium iodide I 131 in breast milk may reach concentrations equal to or greater than concentrations in maternal plasma.

Published studies show that sodium iodide I 131 is transferred into breast milk and is taken up by the thyroid of the breastfed infant.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use. Because of the increased absorbed radiation dose for I 131 in pediatric patients, the risks and benefits from diagnostic use of DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC must be assessed before consideration is given to the use of this radiopharmaceutical in pediatric patients. Pediatric patients are at an increased lifetime risk for malignancy from radiation exposure.

7.1.4 Geriatrics

Geriatrics (> 65 years of age): Clinical experience has not identified differences in safety or effectiveness in geriatric patients compared to younger patients. However, elderly patients are more likely to have decreased renal function and radiation exposure is greater in patients with impaired renal function (see 7.1.5 Renal Impairment).

7.1.5 Renal Impairment

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC is primarily excreted by the kidneys. Radiation exposure following DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC is greater in patients with impaired renal function compared to patients with normal renal function. Renal function impairment decreases excretion of sodium iodide I 131 and increases the radiation exposure and risk of radiation toxicity.

8 ADVERSE REACTIONS

8.1 Adverse Drug Reaction Overview

The following clinically significant adverse reactions are described below and elsewhere in the labelling:

- Immune (see 7 WARNINGS AND PRECAUTIONS)
- Radiation Exposure (see 7 WARNINGS AND PRECAUTIONS)

- Renal Impairment (see 7.1 Special Populations)
- Reproductive Health: Female and Male Potential (see 7 WARNINGS AND PRECAUTIONS)
- Risk of Radioactive Uptake Measurement and Imaging Misinterpretation (see 7 WARNINGS AND PRECAUTIONS)

8.5 Post-Market Adverse Reactions

The following adverse reactions have been reported during post-approval use of sodium iodide I 131 capsules diagnostic (Table 6). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Table 6. Postmarket Adverse Reactions by System Organ Class

System Organ Class*	Symptoms*
Gastrointestinal disorders	Diarrhea, nausea, vomiting
General disorders and administration site conditions	Local swelling of thyroid
Immune system disorders	Hypersensitivity reactions
Skin and subcutaneous tissue disorders	Erythema, hives, itching, rash

* In alphabetical order

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

- Many drugs and iodide-containing foods interfere with the accumulation of radioiodide by the thyroid. Review the patient's history, current medications, and recent diagnostic tests prior to the administration of sodium iodide I 131 [see 7 WARNINGS AND PRECAUTIONS].
- Advise patients to discontinue taking the following products before they undergo the procedure as shown in Table 7.

The drugs listed in Table 7 are based on either drug interaction case reports or studies, or potential interactions. Patients who are using prescription drugs are required to discontinue interfering agents before they undergo the procedure.

Table 7. Pharmaceuticals / OTCs / Agents Blocking Radioiodine Uptake

Type of Medication	Recommended time of withdrawal
Thionamide medications (e.g., propylthiouracil, methimazole, carbimazole)	3 days
Multivitamins containing iodide	10 days
Natural or synthetic thyroid hormones triiodothyronine thyroxine	 2 weeks 4 weeks
Kelp, agar, carrageenan, Lugol solution	3 weeks
Saturated solution of potassium iodide	3 weeks
Topical iodide (e.g., surgical skin preparation)	3 weeks
Intravenous radiographic contrast agents Water soluble Lipophilic	 2 months 6 months
Amiodarone	6 months

9.5 Drug-Food Interactions

Many iodide-containing foods (goitrogenic foods) interfere with the accumulation of radioiodide by the thyroid. Advise patients to maintain a low-iodide diet two weeks prior to radioiodide administration [Iodide-containing foods such as iodized salt, dairy products, egg yolks, seafood, turkey and liver] and continue for several days during the uptake or imaging process.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Iodide is actively transported by the sodium-iodide symporter (NIS) protein, in thyroid follicular cells. Iodide is concentrated in follicular cells to levels up to 50 times higher than in the plasma. Iodide is metabolically oxidized by thyroid peroxidase to iodinium (I+) which in turn iodinates tyrosine residues of thyroglobulin (tri or tetra-iodinated tyrosine). The gamma emission of Iodine I 131 is imaged or counted.

10.2 Pharmacodynamics

The relationship between the extent of iodide I 131 exposure and pharmacologic effects has not been explored in clinical trials.

10.3 Pharmacokinetics

Absorption: Sodium iodide is rapidly absorbed from the gastrointestinal tract. Following oral adminitration Sodium Iodide I 131 Capsules Diagnostic, 90% of the administered radioactivity of sodium iodide I 131 is systematically absorbed in the first 60 minutes.

Distribution: Following absorption, iodide I 131 is distributed within the extra-cellular space. It is actively transported by the sodium-iodide symporter (NIS) protein, and binds to thyroglobulin resulting in accumulation in the thyroid. The thyroid uptake of iodide is usually increased in hyperthyroidism and in goiter, and is decreased in hypothyroidism. It should be noted that the uptake of radioactive iodide is a function of stable iodide concentration in the serum and the functional state of the thyroid. About 10% to 25% of the administered dose is selectively concentrated from the blood by the normal thyroid gland. The iodine concentrating mechanism of the thyroid, termed the iodide trap or pump, accounts for an iodide concentration of some 25 times plasma levels, but may increase as much as 50 times under certain conditions. Iodine is also accumulated but not organified by the stomach mucosa, choroid plexus, breast, salivary glands, liver, gall bladder, and kidneys; the remainder within the extracellular fluid.

Metabolism: Trapped iodide is oxidized to iodine and organically incorporated so rapidly that the iodide trap of the thyroid contains less than 0.2% free iodide in comparison to the organically bound iodine. This process results in further concentration of iodine in the thyroid gland to about 50 times that in the blood.

The thyroid uses iodine to form thyroid hormones (thyroxine [T4], triiodothyronine [T3]) by iodination of tyrosine residues in thyroiglobulin. The iodinated organic compounds chiefly consist of thyroxine (T4) and triiodothyronine (T3), which are bound by thyroglobulin in the follicular colloid. T4 and T3 are released by enzymatic proteolysis of thyroglobulin into the blood where they are specifically bound and transported by plasma thyroid binding proteins. These reactions are primarily under the control of anterior pituitary gland release of thyroid stimulating hormone (TSH) and hypothalamic thyroid release factor (TRF).

In thyroidal follicular cells iodide is oxidized through the action of thyroid peroxidase to iodinium (I+) which in turn iodinates tyrosine residues of thyroglobulin.

Elimination: Sodium Iodide I 131 is excreted in urine and feces. The normal range of urinary excretion is 37 to 75% of the administered dose, varying with the thyroid and renal function of the patient. Approximately 60% to 90% of the administered dose is excreted in the urine within 24 hours. Fecal excretion is about 10%.

11 STORAGE, STABILITY AND DISPOSAL

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES / SOLUTION, USP DIAGNOSTIC should be stored upright at all times at or below room temperature (2 °C to 30 °C). Expiry date is stated on the label accompanying the product vial.

12 SPECIAL HANDLING INSTRUCTIONS

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to occupational workers.

Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclide, and whose experience and training have been approved by the appropriate governmental agency authorised to license the use of radionuclides.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	Sodium Iodide (^{131}I)
Chemical name:	Sodium Iodide (^{131}I)
Molecular formula and molecular mass:	NaI; 153.99 g/mol
Physicochemical properties:	White granular or colorless crystals Odorless Solubility: 184 g/100 mL water @ 25°C

Product Characteristics

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC are color-coded gelatin capsules containing sodium iodide I-131 for diagnostic use by oral administration. Each capsule contains no-carrier added sodium iodide I 131, disodium edetate dihydrate USP as a stabilizer, sodium thiosulfate pentahydrate USP as a reducing agent, and dibasic sodium phosphate anhydrous USP.

DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC is an aqueous solution containing sodium iodide I-131 for diagnostic use by oral administration. Each mL of aqueous solution contains disodium edetate dihydrate as stabilizer, sodium thiosulfate pentahydrate USP as a reducing agent and disodium phosphate anhydrous. The pH of the solution is between 7.5 and 9. The specific activity of sodium iodine I-131 is designated as carrier-free.

Sodium Iodide Solution is designated chemically as Na^{131}I and has a molecular weight of 153.99, CAS 7790-26-3.

14 CLINICAL TRIALS

The clinical trial data on which the original indications were authorized is not available.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Species	Route of administration	LD_{50}
Mice	Intraperitoneal	1690 ± 85 mg/kg
Mice	Intravenous	> 1500 mg/kg
Mice	Oral	1650 ± 90 mg/kg

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC (Sodium Iodide I 131 Capsules, USP for oral use)

DRAXIMAGE® SODIUM IODIDE I 131 SOLUTION, USP DIAGNOSTIC (Sodium Iodide I 131 Solution, USP for oral use)

Read this carefully before you receive DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC.

Serious Warnings and Precautions

- DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC should be used only by those health professionals who are appropriately qualified in the use of radioactive prescribed substances in or on humans.

What is DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC used for?

- DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC is indicated for evaluation of thyroid function;
- Imaging of the thyroid gland.

How does DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC work?

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC is a radioactive form of iodide. Iodide is an essential element that is part of our normal diet and is used by the thyroid to make thyroid hormone. About 10% to 20% of the administered dose is selectively concentrated from the blood by the normal thyroid gland. The radioactive iodide in DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC is captured by the thyroid and can be used for the evaluation of thyroid function or imaging of the thyroid gland.

What are the ingredients in DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC?

Medicinal ingredient: Sodium Iodide (^{131}I)

Non-medicinal ingredients: **Capsules:** Each gelatin capsule also contains: Disodium edetate dihydrate, sodium phosphate dibasic and sodium thiosulfate pentahydrate.

Solution: Each mL of solution contains: Disodium edetate dihydrate, disodium phosphate anhydrous and sodium thiosulfate pentahydrate, water.

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC comes in the following dosage forms:

- Capsules: 3.7 MBq (100 microCi) per capsule
- Solution: 74 MBq to 925 MBq (2 mCi to 25 mCi) per vial

Do not use DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC if:

- you are pregnant;
- you are breastfeeding;
- you are vomitting, have diarrhea;
- you are taking anti-thyroid medication.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC. Talk about any health conditions or problems you may have, including if you:

- are or think you might be pregnant;
- are a nursing mother who is breast feeding an infant;
- are feeling nauseous, have been vomitting, or have diarrhea;
- have kidney problems;
- are allergic to sulfites. DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES, USP DIAGNOSTIC may contain sodium thiosulfate;
- recently received medication containing iodide including contract dye for x-rays or CT scans.

Other warnings you should know about:

- Hydrate before and after administration of Sodium Iodide I 131 and void frequently to ensure rapid excretion.
- Fast at least 2 hours before and 2 hours after administration to ensure absorption.
- Maintain a low-iodine diet two weeks prior to radioiodine administration and continue for several days during the uptake or imaging process.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC:

- Thionamide medications (e.g., propylthiouracil, methimazole, carbimazole);
- Multivitamins containing iodide;
- Natural or synthetic: thyroid hormones, triiodothyronine, thyroxine;
- Kelp, agar, carrageenan, Lugol solution;
- Saturated solution of potassium iodide;
- Topical iodide (e.g. surgical skin preparation);
- Intravenous radiographic contrast agents: Water soluble, Lipophilic;
- Amiodarone.

A number of prescription and non-prescription drugs may interact with DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC. Make sure your doctor knows all of the drugs you are taking.

How to take DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC:

DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC will be given to you by a health professional who is experienced in the use of radiopharmaceuticals.

Overdose:

If you think you, or a person you are caring for, have received too much DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC, contact your healthcare professional, hospital emergency department or Canadian Nuclear Safety Commission immediately, even if there are no symptoms.

What are possible side effects from using DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC?

These are not all the possible side effects you may feel when taking DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Nausea, vomiting and diarrhea	X	
Local thyroid swelling	X	

Hypersensitivity reactions	**X**	
itching , rash, hives and erythema	**X**	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/drug.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store upright at all times at or below room temperature (2 °C to 30 °C).

Keep out of reach and sight of children.

If you want more information about DRAXIMAGE® SODIUM IODIDE I 131 CAPSULES or SOLUTION, USP DIAGNOSTIC:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's https://www.jubilantradiopharma.com or by calling 1-888-633-5343 / 514-630-7080.

This leaflet was prepared by:

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Last Revised: