

PRODUCT MONOGRAPH

HIGH PURITY INDIUM CHLORIDE In 111 STERILE SOLUTION

(Indium 111 Trichloride)

Solution, 10 mCi per mL

Radiodiagnostic Agent

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Date of Revision: April 26th, 2019

Distributed by:
Curium Canada Inc.
Laval, QC, H7T-2R3
CANADA

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Control No: 225108

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High Purity Indium Chloride In 111 Sterile Solution

Indium 111 Trichloride

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Non-medicinal Ingredients
Used <i>in vitro</i> as radiolabeling agent	Solution, 10 mCi per mL	The vial contains hydrochloric acid. <i>For a complete listing see DOSAGE FORMS, COMPOSITION AND PACKAGING.</i>

DESCRIPTION

High Purity Indium In 111 Chloride Sterile Solution for use as a radiolabeling agent, is a sterile, non-pyrogenic (less than 5 endotoxin units/mL), solution of indium 111 chloride (InCl_3) with a pH of 1.1 to 1.4. At the time of calibration, each one-half millilitre contains 185 megabecquerels (5 millicuries) of indium 111 chloride (InCl_3). At time of calibration, it contains not less than 99.925% indium 111 and not more than 0.075% indium 114m and zinc (zinc 65) combined. At time of expiration, it contains not less than 99.85% indium 111 and not more than 0.15% indium 114m and zinc (zinc 65) combined. No carrier has been added and the preparation contains no bacteriostatic preservative. High Purity Indium In 111 Chloride Sterile Solution in unit dose is a radiolabeling agent for those drugs and biologics which have been approved for use with this product.

High Purity Indium Chloride In 111 Sterile Solution contains extremely low levels of the following metallic impurities: copper, iron, cadmium, lead, zinc, nickel and mercury.

Physical Characteristics

Indium 111 decays by electron capture with a physical half-life of 2.8 days¹. The principal gamma photons are listed in Table 1.

Table 1. Principal Radiation Emission Data¹

Radiation	Mean % Per Disintegration	Mean Energy (keV)
Gamma-2	90.2	171.3
Gamma-3	94.0	245.4

External Radiation

The specific gamma ray constant for Indium 111 is $23.0 \mu\text{C.kg}^{-1}.\text{MBq}^{-1}.\text{h}^{-1}$ (3.21 R/mCi-hr) at 1 cm. The first half value layer is 0.026 cm of lead. A range of values for the relative attenuation of the radiation resulting from the interposition of various thicknesses of lead is shown in Table 2. For example, the use of 0.777 cm of lead will attenuate the radiation emitted by a factor of about 1000.

Table 2. Radiation Attenuation by Lead Shielding²

Shield Thickness (Pb), (cm)	Coefficient of Attenuation
0.026	0.5
0.196	10^{-1}
0.482	10^{-2}
0.777	10^{-3}

To correct for physical decay of this radionuclide, the fraction that remains at selected intervals after calibration are shown in Table 3.

Table 3. Physical Decay Chart, Indium 111: Half-life 2.8 Days

Hours	Fraction Remaining	Hours	Fraction Remaining
-72	2.10	0*	1.00
-60	1.85	6	0.94
-48	1.64	12	0.88
-36	1.45	24	0.78
-24	1.28	36	0.69
-12	1.13	48	0.61
-6	1.06	72	0.48

* Calibration time

INDICATIONS AND CLINICAL USE

High Purity Indium Chloride In 111 Sterile Solution is indicated for radiolabeling drug and biologic preparations approved for labeling with High Purity Indium Chloride In 111 Sterile Solutions.

Please refer to the package insert of the product to be radiolabeled for information regarding the indications and clinical use of the radiolabeled product.

CONTRAINDICATIONS

Please refer to the package insert for the product to be radiolabeled for this information.

Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container should advise their physician. For a complete listing, see **DOSAGE FORMS, COMPOSITION AND PACKAGING**.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Radiopharmaceuticals should be used under the supervision 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 government agency authorized to license the use of radionuclides.

General

The product should be used under the supervision of a physician who is experienced in the use of radiopharmaceuticals.

The contents of the vial of High Purity Indium Chloride In 111 Sterile Solution is not to be administered directly to humans. This product is intended only to be used as an ingredient for radiolabeling drug and biologic preparations approved for labeling with High Purity Indium Chloride In 111 Sterile Solutions.

Strict aseptic techniques should be used to maintain sterility throughout the procedures for using this product. Do not use after the expiration time and date stated on the label. The contents of the vial are radioactive. Adequate shielding must be maintained at all times.

Carcinogenesis and Mutagenesis

Please refer to the package insert for the product to be radiolabeled for this information.

Contamination

Please refer to the package insert for the product to be radiolabeled for this information on the final drug product.

Special Populations

Pregnant Women

Ideally examinations using radiopharmaceuticals, especially those elective in nature of women of childbearing capability, should be performed during the first ten days following the onset of menses.

Please refer to the package insert for the product to be radiolabeled for this information.

Nursing Women

Please refer to the package insert for the product to be radiolabeled for this information.

Pediatrics (0 - 16 years of age)

Please refer to the package insert for the product to be radiolabeled for this information.

Geriatrics (> 65 years of age)

Please refer to the package insert for the product to be radiolabeled for this information.

ADVERSE REACTIONS

Please refer to the package insert for the product to be radiolabeled for this information.

DRUG INTERACTIONS

Please refer to the package insert for the product to be radiolabeled for this information.

DOSAGE AND ADMINISTRATION

Please refer to the package insert for the product to be radiolabeled for this information.

Instructions for Preparation and Use

The sterile, non-pyrogenic solution of Indium In 111 Chloride Sterile Solution is ready for use in the reconstitution of radiopharmaceutical kits or for use in the manufacture of indium 111 labeled radiopharmaceuticals. Refer to the package insert accompanying the product to be radiolabeled with High Purity Indium Chloride In 111 Sterile Solution. It is essential that the user follows the directions carefully and adheres to strict aseptic technique.

Take precautions to minimize radiation exposure by the use of suitable shielding. Waterproof gloves should be worn while handling the radiodiagnostic reagent.

Directions for Quality Control

Please refer to the package insert for the product to be radiolabeled for instructions on quality control of the final product.

RADIATION DOSIMETRY

Please refer to the package insert for the product to be radiolabeled for this information.

OVERDOSAGE

Please refer to the package insert for the product to be radiolabeled for this information.

ACTION AND CLINICAL PHARMACOLOGY

Please refer to the package insert for the product to be radiolabeled for this information.

STORAGE AND STABILITY

High Purity Indium Chloride In 111 Sterile Solution may be stored at controlled room temperature (20-25°C) with proper radiation shielding. The product must be protected from freezing.

Expiry date: As of 12 noon Central Time, 3 days after calibration.

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.

This radiopharmaceutical product may be received and used 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.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Catalogue Number: 132F0

High Purity Indium Chloride In 111 Sterile Solution (0.5 mL solution in 10 mL vial)

Each rubber-capped unit dose contains indium In 111 chloride (InCl_3) in a sterile, non-pyrogenic solution for use as a radiolabeling agent. The radioactive concentration at time of calibration is 370 MBq/mL (10 mCi/mL). The pH of the solution is 1.1 to 1.4. The amount of radioactivity contained in each vial is 185 MBq (5 mCi) at calibration.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Indium In111 Chloride

Chemical name: Not applicable

Molecular formula and molecular mass: Not applicable

Structural formula: Not applicable

Physicochemical properties: Indium 111 decays by electron capture with a physical half-life of 2.8 days.

Product Characteristics

Indium 111 decays by electron capture with a physical half-life of 2.8 days¹. The principal gamma photons are listed in the table below.

Principal Radiation Emission Data¹

Radiation	Mean % Per Disintegration	Mean Energy (keV)
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External Radiation

The specific gamma ray constant for Indium 111 is $23.0 \mu\text{C} \cdot \text{kg}^{-1} \cdot \text{MBq}^{-1} \cdot \text{h}^{-1}$ (3.21 R/mCi-hr) at 1 cm. The first half value layer is 0.026 cm of lead. A range of values for the relative attenuation of the radiation resulting from the interposition of various thicknesses of lead is shown in the following table. For example, the use of 0.777 cm of lead will attenuate the radiation emitted by a factor of about 1000.

Radiation Attenuation by Lead Shielding ²

Shield Thickness (Pb), cm	Coefficient of Attenuation
0.026	0.5
0.196	10 ⁻¹
0.482	10 ⁻²
0.777	10 ⁻³

To correct for physical decay of this radionuclide, the fraction that remains at selected intervals after calibration are shown in the table below.

Physical Decay Chart, Indium 111: Half-life 2.8 Days

Hours	Fraction Remaining	Hours	Fraction Remaining
-72	2.10	0*	1.00
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-24	1.28	36	0.69
-12	1.13	48	0.61
-6	1.06	72	0.48

* Calibration time

CLINICAL TRIALS

Please refer to the package insert for the product to be radiolabeled for this information.

DETAILED PHARMACOLOGY

See ACTION AND CLINICAL PHARMACOLOGY in PART I of the Product Monograph.

TOXICOLOGY

Please refer to the package insert for the product to be radiolabeled for this information.

REFERENCES

1. Stabin MG, da Luz CQPL. Decay Data for Internal and External Dose Assessment, Health Physics. 83(4):471-475, 2002.
2. Smith David S., Stabin MG. Exposure Rate Constants and Lead Shielding Values for Over 1,100 Radionuclides, Health Physics. 102(3):271-291, March 2012.

PART III: CONSUMER INFORMATION**High Purity Indium Chloride In 111 Sterile Solution**
Indium 111 Trichloride

This leaflet is part III of a three-part "Product Monograph" published when High Purity Indium In 111 Chloride Solution was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about High Purity Indium In 111 Chloride Solution. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is used for:

High Purity Indium In 111 Chloride Solution is used with other medicines to make radioactive tracers used in Nuclear Medicine scans to help your doctor make a diagnosis.

Please refer to the package insert of the medicine for information on what the radioactive tracer made with High Purity Indium In 111 Chloride Solution is used for.

What it does:

After the radioactive tracer is injected, your doctor will take a picture (scan) with a special camera to show the areas where the radioactivity collects in your body. These pictures will help your doctor make the diagnosis.

Please refer to the package insert of the medicine for information on what the radioactive tracer made with High Purity Indium In 111 Chloride Solution does.

What the medicinal ingredient is:

Indium In 111 Chloride

What the important non-medicinal ingredients are:

Hydrochloric Acid

For a full listing of non-medicinal ingredients see Part I of the product monograph.

WARNINGS AND PRECAUTIONS

Since High Purity Indium In 111 Chloride Solution is a radiopharmaceutical, it can only be used by a healthcare professional who is specially trained and experienced in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

BEFORE you receive the radioactive tracer made with High Purity Indium In 111 Chloride Solution talk to your doctor or pharmacist if:

- You had any allergic reaction to this radiopharmaceutical in the past or its ingredients

Please refer to the package insert of the medicine used with High Purity Indium In 111 Chloride Solution for information regarding:

- Use during pregnancy.
- Use during breastfeeding
- Safety precautions

INTERACTIONS WITH THIS MEDICATION

Please refer to the package insert of the medicine used with High Purity Indium In 111 Chloride Solution for this information.

PROPER USE OF THIS MEDICATION

Radioactive tracers made with High Purity Indium In 111 Chloride Solution will be administered under the supervision of a health professional who is trained and experienced in the safe use of radiopharmaceuticals.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Please refer to the package insert of the medicine used with High Purity Indium In 111 Chloride Solution for this information

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call (toll-free) at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax (toll-free) to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON, K1A 0K9**

You can also report suspected adverse reactions directly to Curium Canada Inc. by one of the following 2 ways:

- Call (toll-free) to 1-866-789-2211
- Mail to: **Curium Canada Inc.
c/o Pharmacovigilance Department
2572 Boul. Daniel-Johnson, Suite 248
Laval, QC, H7T-2R3**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

Artwork revision: R02/2019

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MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Curium Canada Inc. at 1-866-885-5988.

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This leaflet was prepared by Curium Canada Inc.

Last revised: April 26th, 2019

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Curium Canada Inc.
Laval, QC, H7T-2R3
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DIN: 02329468