

INDIUM IN 111 CHLORIDE- indium in 111 chloride solution
Curium US LLC

Indium In 111
Chloride Sterile Solution

Rx only

Diagnostic - For use only in radiolabeling ProstaScint™ (Capromab Pendetide).

Radioimmunotherapy - For use only in radiolabeling Zevalin™ (Ibritumomab Tiuxetan).

FOR SINGLE USE ONLY

DESCRIPTION

Indium In 111 Chloride Sterile Solution is indicated for radiolabeling ProstaScint™ preparations used for in vivo diagnostic imaging procedures. It is also indicated for radiolabeling Zevalin™ preparations used for Radioimmunotherapy procedures. It is supplied as a sterile, non-pyrogenic solution of Indium In 111 Chloride in 0.05 molar hydrochloric acid. No carrier has been added to the solution. Each 0.5 milliliter of the solution contains 185 megabequerels (5 millicuries) of Indium In 111 Chloride at time of calibration (specific activity of >1.85 GBq/μg Indium; >50 mCi/μg Indium at this time of calibration). The solution pH is 1.1 to 1.4.

Radionuclidic Purity

Indium In-111 is cyclotron produced by the proton irradiation ((p,2n) reaction) of cadmium Cd-112 enriched target. At time of calibration, it contains not less than 99.925% indium In-111 and, not more than 0.075% indium In-114m and zinc Zn-65 combined. At the time of expiration, it contains not less than 99.85% indium 111 and not more than 0.15% indium In-114m and zinc Zn-65 combined. No carrier has been added.

Radiochemical Purity

At the time of calibration, the Indium In 111 Chloride Sterile Solution contains not less than 95% of the Indium present as ionic In³⁺.

Chemical Purity

Indium In 111 Chloride Sterile Solution is tested for the following metallic impurities: copper, iron, cadmium, lead, zinc, nickel, and mercury, and contains extremely low levels of these metals. The sum of the individual impurity ratios for the metals listed is not more than 0.60 ppm.

Physical Characteristics

Indium In-111 decays by electron capture to cadmium Cd-111 (stable) with a physical half-life of 67.32 hours (2.81 days) (see Table 2)¹. Photons useful for detection and imaging are listed in Table 1.

Table 1. Principal Radiation Emission Data*

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

* Kocher, David C., "Radioactive Decay Data Tables", DOE/TIC-11026, 115 (1981).

¹ From Radiopharmaceutical Internal Dosimetry Information Center, Oak Ridge Associated Universities, Oak Ridge, TN 37831-0117, February 1985.

External Radiation

The exposure rate constant for 37 MBq (1 mCi) of indium In-111 is 8.3×10^{-4} C/kg/hr (3.21 R/hr) at 1 cm. The specific gamma ray constant for indium In-111 is 3.21 R/hr-mCi @ 1 cm¹. The first half-value thickness of lead (Pb) is 0.023 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in *Table 2*. For example, the use of 0.834 cm of Pb will decrease the external radiation exposure by a factor of about 1000.

Table 2. Indium In-111 Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.023	0.5
0.203	10^{-1}
0.513	10^{-2}
0.834	10^{-3}
1.12	10^{-4}

These estimates of attenuation do not take into consideration the presence of longer-lived contaminants with higher energy photons, namely indium In-114m.

To correct for physical decay of indium In-111, the fractions that remain at selected intervals before and after calibration time are shown in *Table 3*.

Table 3. Indium In-111 Physical Decay Chart; Half-Life 67.32 hours (2.81 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

CLINICAL PHARMACOLOGY

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

INDICATIONS AND USAGE

Indium In 111 Chloride Sterile Solution is indicated for radiolabeling ProstaScint preparations used for in vivo diagnostic imaging procedures. It is also indicated for radiolabeling Zevalin preparations used for Radioimmunotherapy procedures. Please refer to the package insert for ProstaScint or Zevalin for information on the final drug product.

CONTRAINDICATIONS

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

WARNINGS

CONTENTS OF THE VIAL OF INDIUM In 111 CHLORIDE SOLUTION ARE INTENDED ONLY TO BE USED AS AN INGREDIENT FOR RADIOLABELING PROSTASCINT FOR USE IN IN VIVO DIAGNOSTIC IMAGING PROCEDURES OR TO BE USED AS AN INGREDIENT FOR RADIOLABELING ZEVALIN™ FOR USE IN RADIOIMMUNOTHERAPY PROCEDURES, AND ARE NOT TO BE ADMINISTERED DIRECTLY TO HUMANS.

PRECAUTIONS

General

Caution must be used to maintain proper aseptic technique while withdrawing and transferring contents of the Indium Chloride solution vial.

Do not use after expiration time and date indicated on vial label.

Contents of the vial are radioactive and adequate shielding and handling precautions must be maintained at all times.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

Pregnancy Category

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

Nursing Mothers

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

Pediatric Use

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

ADVERSE REACTIONS

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

DOSAGE AND ADMINISTRATION

Radiation Dosimetry

Please refer to the package insert for ProstaScint or Zevalin for this information on the final drug product.

HOW SUPPLIED

Indium In 111 Chloride Sterile Solution is supplied in 10 mL vials containing 0.5 mL of solution. It is a sterile non-pyrogenic solution in 0.05 molar hydrochloric acid. No carrier is added to the solution. Each 0.5 mL contains 185 megabequerels (5 millicuries) of Indium In 111 Chloride at time of calibration. The pH of the solution is 1.1 to 1.4.

Special Storage and Handling

The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained. Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Storage and disposal of Indium In 111 Chloride Sterile Solution should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of the radionuclide.

The vial should be kept inside its transportation shield whenever possible and should be handled with forceps when contents are being removed.

Pharmacovigilance:1-866-789-2211

ProstaScint is a trademark of EUSA Pharma (USA), Inc.

Zevalin is a trademark of RIT Oncology, LLC.

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Manufactured by:

Curium US LLC

Maryland Heights, MO 63043

Made in USA

A132I0

R12/2018

CURIUM™

PRINCIPAL DISPLAY PANEL

Indium In 111 Chloride Sterile Solution

Sterile, Non-Pyrogenic Solution

Contains no Bacteriostatic Preservative

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

SINGLE DOSE - NOT FOR DIRECT ADMINISTRATION

NO CARRIER ADDED

FOR USE ONLY IN RADIOLABELING

ProstaScint™ (Capromab Pendetide),

and Zevalin™ (Ibritumomab Tiuxetan)

SEE PACKAGE INSERT FOR INFORMATION

Rx only

WARNING: Radioactive drugs must be handled only by qualified personnel in conformity with regulations of the U.S. Nuclear Regulatory Commission or state regulatory agencies where applicable. Bottle containing drug should be kept in this container or within heavier shield.

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Curium US LLC
Maryland Heights, MO 63043
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CURIUM™

CAUTION RADIOACTIVE MATERIAL

A132C0

R12/2018

Indium In 111 Chloride Sterile Solution		Total Act.	MBq	Total Act.	MBq
R12/2018	Sterile, Non-Pyrogenic Solution	(mCi)	(mCi)
	Contains no Bacteriostatic Preservative	As of 1800 CT		As of 1800 CT	
	Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)				
	SINGLE DOSE - NOT FOR DIRECT ADMINISTRATION				
	NO CARRIER ADDED				
A132C0	FOR USE ONLY IN RADIOLABELING	Volume	mL	Volume	mL
	ProstaScint™ (Capromab Pentetide),	Conc.	MBq/mL	Conc.	MBq/mL
	and Zevalin™ (Ibritumomab Tiuxetan)	(mCi/mL)	(mCi/mL)
	SEE PACKAGE INSERT FOR INFORMATION				
	Rx only	Exp. 1800 CT		Exp. 1800 CT	
WARNING: Radioactive drugs must be handled only by qualified personnel in conformity with regulations of the U.S. Nuclear Regulatory Commission or state regulatory agencies where applicable. Bottle containing drug should be kept in this container or within heavier shield.		Lot		Lot	
Manufactured by: Curium US LLC Maryland Heights, MO 63043 Made in USA					
CURIUM™				Indium In 111 Chloride Sterile Solution	
				CURIUM™	

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INDIUM IN 111 CHLORIDE

indium in 111 chloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69945-132
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INDIUM CHLORIDE IN-111 (UNII: 58TD96H03I) (INDIUM CATION IN-111 - UNII: WJZ06C0H8L)	INDIUM CATION IN-111	10 mCi in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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HYDROCHLORIC ACID (UNII: QTT17582CB)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69945-132-06	1 in 1 CAN	12/07/2007	
1		0.5 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA019841	12/07/2007	

Labeler - Curium US LLC (079875617)