

**INDICLOR- indium chloride in-111 solution**  
**Medi-Physics Inc.**

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**INDICLOR™**

**High Purity Indium Chloride In-111 Sterile Solution**  
**Diagnostic—For use in Radiolabeling**  
**ProstaScint and Zevalin**

**For single dose, single use only**

**DESCRIPTION**

INDICLOR Indium In-111 Chloride is a diagnostic radiopharmaceutical intended for radiolabeling ProstaScint (capromab pendetide) used for *in vivo* diagnostic imaging procedures and for radiolabeling Zevalin (ibritumomab tiuxetan) in preparations used for radioimmunotherapy procedures. It is supplied as a sterile, pyrogen-free solution of Indium (<sup>111</sup>In) Chloride in 0.04M HCl. Each milliliter is supplied at a radioactive concentration of 370 MBq, 10 mCi of Indium In-111 Chloride at time of calibration (no carrier added, with specific activity of > 1.85 GBq/μg Indium, > 50 mCi/μg Indium at time of calibration). The pH of the solution is about 1.4.

**RADIONUCLIDIC PURITY**

A Cadmium Cd-112 enriched target is bombarded in a cyclotron to produce Indium In-111 by the (p,2n) reaction. The bombardment conditions, the energy of the proton beam and the length of the bombardment are chosen to ensure an Indium In-111 yield of high radionuclidic purity. Radionuclidic purity is checked at release particularly for the presence of Indium In-114. The relative proportion of this impurity increases, after release of the batch, as a result of its longer half-life. Because of its beta-emitting component and its potentially high organ dose contribution, Indium In-114m is particularly important if present above carefully controlled levels.

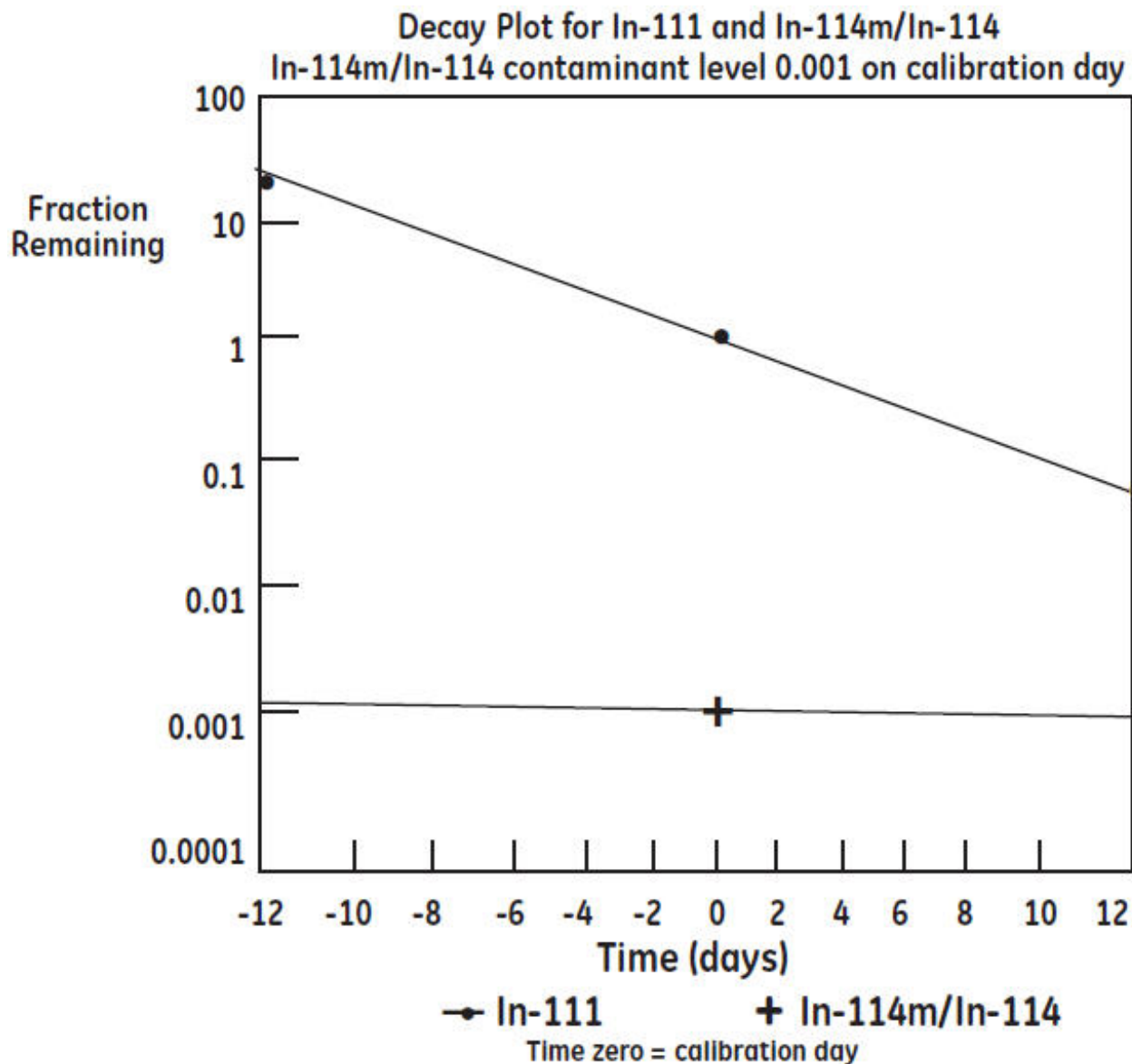
Release specifications:

< 0.08% Indium In-114m at calibration time

< 0.16% Indium In-114m at expiration time

**RADIOCHEMICAL PURITY**

Release specification: Not less than 95% Indium present as ionic In<sup>3+</sup>.



### PHYSICAL CHARACTERISTICS

Indium In-111 decays by electron capture with a physical half-life of 67.2 hours (2.8 days). The energies of the photons that are useful for detection and imaging studies are listed in Table 1.

**Table 1. Principal Radiation Emission Data\***

Radiation	Mean%/Disintegration	Mean Energy (keV)
Gamma 2	90.2	171.3
Gamma 3	94	245.4

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

### EXTERNAL RADIATION

The exposure rate constant for 37 MBq, 1 mCi Indium In-111 is  $8.3 \times 10^{-4}$  C/kg/hr, 3.21 R/hr at 1 cm. The first half value thickness of lead (Pb) for Indium In-111 is 0.023 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.834 cm of lead will decrease the external radiation exposure by a factor of about 1,000.

**Table 2. Indium-111 Radiation Attenuation of Lead Shielding\***

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.023	0.5
0.203	10 <sup>-1</sup>
0.513	10 <sup>-2</sup>
0.834	10 <sup>-3</sup>
1.12	10 <sup>-4</sup>

\* Data supplied by Oak Ridge Associated Universities, Radiopharmaceutical Internal Dose Information Center, 1984.

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

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

**Table 3. Indium In-111 Physical Decay Chart, Half-Life 67.2 Hours (2.8 days)**

Hours	Fraction Remaining	Hours	Fraction Remaining
-48	1.64	18	0.83
-42	1.54	24	0.78
-36	1.44	30	0.74
-30	1.36	36	0.69
-24	1.28	42	0.65
-18	1.20	48	0.61
-12	1.13	54	0.58
-6	1.06	60	0.54
0*	1.00	66	0.51
6	0.94	72	0.48
12	0.88		

\* 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

INDICLOR Indium In-111 Chloride is indicated for radiolabeling of ProstaScint (capromab pendetide) in preparations used for *in vivo* diagnostic imaging procedures. IndiclOr is also indicated for radiolabeling Zevalin (ibritumomab tiuxetan) in preparations used for radioimmunotherapy procedures. Please refer to the package insert for ProstaScint or Zevalin for information regarding the radiolabeled product.

## CONTRAINDICATIONS

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

## **WARNINGS**

The contents of the vial of INDICLOR Indium In-111 Chloride solution are intended only to be used as an ingredient for radiolabeling ProstaScint used for *in vivo* diagnostic imaging procedures and for radiolabeling Zevalin in preparations used for radioimmunotherapy procedures.

**Indiclor is not to be administered directly to humans.**

## **PRECAUTIONS**

### **General**

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, 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.

## **GERIATRIC 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**

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

## **RADIATION DOSIMETRY**

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

## **STERILITY AND APYROGENICITY**

This product is terminally sterilized by autoclave. Apyrogenicity is confirmed before release by a Limulus test.

## **HOW SUPPLIED**

INDICLOR Indium-111 Chloride is supplied in a 2 mL vial containing 0.5 milliliters, 185 MBq, 5.0 mCi of Indium In-111 at calibration time. This packaging design has been carefully selected to minimize leaching of cationic and anionic impurities into the product during transport and storage.

NDC 17156-523-01

## **SPECIAL HANDLING AND STORAGE**

Store at room temperature 15°-25°C (59°-77°F).

This preparation is approved for use by persons licensed by the Illinois Emergency Management Agency pursuant to 32 IL. Adm. Code Section 330.260(a) and 335.4010 or equivalent licenses of the Nuclear Regulatory Commission or an Agreement State.

It is recommended that the vial be kept inside its transportation shield whenever possible and that it be handled with forceps when doses are being removed.

INS.1PA — Wednesday Calibration

INS.1PAF — Saturday Calibration

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

Zevalin® is a registered trademark of Spectrum Pharmaceuticals, Inc.

Manufactured by:

**GE Healthcare**

Medi-Physics, Inc.

Arlington Heights, IL 60004 U.S.A.

**Customer Service: 1-800-292-8514**

**Professional Services: 1-800-654-0118**

INDICLOR is a trademark of GE Healthcare.

GE and the GE Monogram are trademarks of General Electric Company.

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43-0523

Revised April 2013

Product Codes: INS. 1PA/INS. 1PAF

## **PRINCIPAL DISPLAY PANEL - 2 mL Vial Label**

GE Healthcare

**INDICLOR™ Indium (<sup>111</sup> In) Chloride**

**GE**

1NS1PA

**Rx ONLY.** Sterile, Non-pyrogenic Solution in 0.04M HCl

NOT FOR DIRECT ADMINISTRATION.

Do not use after 3 days from Reference date. No carrier added.

Storage: Ambient Temperature 15°-25°C (59°-77°F).

For use when radiolabeling Monoclonal Antibodies. Refer to package insert.

185 MBq, 5 mCi, 370 MBq/mL 10 mCi/mL at 0600hrs CST on reference

0.5mL Single Dose vial <0.2 µg In/mL

Mfd by: **GE Healthcare**, Medi-Physics, Inc., Arlington Heights, IL 60004 U.S.A.

41-0523

GE Healthcare

**INDICLOR™** Indium (<sup>111</sup>In) Chloride



INS1PA

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41-0523

## INDICLOR

indium chloride in-111 solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:17156-523
Route of Administration	INTRAVENOUS	DEA Schedule	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Indium Chloride In-111 (Indium Cation in-111)	Indium Cation in-111	5 mCi in 0.5 mL

### Inactive Ingredients

Ingredient Name	Strength
Hydrochloric Acid	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17156-523-01	1 in 1 CONTAINER		
1		2 mL in 1 VIAL, SINGLE-DOSE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019862	12/29/1992	

**Labeler** - Medi-Physics Inc. (095263729)

### Establishment

Name	Address	ID/FEI	Business Operations
Medi-Physics Inc.		095263729	MANUFACTURE(17156-523), RELABEL(17156-523), REPACK(17156-523), ANALYSIS(17156-523), API MANUFACTURE(17156-523)

Revised: 10/2013

Medi-Physics Inc.