DRAFT

INDICLOR™

High Purity Indium Chloride In-111 Sterile Solution

Diagnostic - For Use in Radiolabeling OncoScint®, ProstaScint™, and Zevalin™

(see package insert for indications)

For single dose, single use only

R_x ONLY

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

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DESCRIPTION

INDICLOR Indium In-111 Chloride is a diagnostic radiopharmaceutical intended for radiolabeling OncoScint (satumomab pendetide) or 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 (^{111}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.

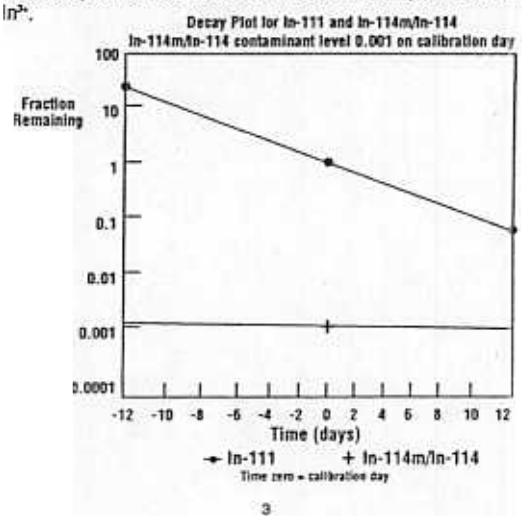
Release specifications:

< 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^{3+}.



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[1]

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

[1]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 x 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[2]

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}

[2]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 OncoScint, ProstaScint or Zevalin for this information on the final drug product.

INDICATIONS AND USAGE

INDICLOR Indium In-111 Chloride is indicated for radiolabeling of monoclonal antibodies in preparations used for *in vivo* diagnostic imaging procedures. Indiclor is also indicated for radiolabeling Zevalin in preparations used for radioimmunotherapy procedures. Please refer to the package insert for monoclonal antibody preparations for information regarding the radiolabeled product.

CONTRAINDICATIONS

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

PREGNANCY CATEGORY

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

NURSING MOTHERS

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

PEDIATRIC USE

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

GERIATRIC USE

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

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

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

RADIATION DOSIMETRY

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

STERILITY AND APYROGENICITY

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

HOW SUPPLIED

INDICLOR Indium-111 Chloride is supplied in 1 mL vials containing 0.2 milliliters, 74 MBq, 2.0 mCi or 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.

SPECIAL HANDLING AND STORAGE

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

This radiopharmaceutical is licensed by Illinois Department of Nuclear Safety for distribution to persons licensed pursuant to 32 Ill. Adm. Code 330.260(a) and Part 335, Subpart E, 335.4010, or under equivalent licenses of an Agreement State or a Licensing 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

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