**Indium In 111 Chloride Sterile Solution**

**Rx Only.**

Diagnostic - For use only in radiolabeling OncoScint® CR/OV (Satumomab Pendetide) and ProstaScint® (Capromab Pendetide).

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

**DESCRIPTION:**

Indium In 111 Chloride Sterile Solution is indicated for radiolabeling OncoScint CR/OV and 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 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.

**RADIATION METRICS**

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 99.95% Indium in 111 and, not more than 0.05%; indium in 114 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.

**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 these metals 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). Photons useful for detection and imaging are listed in Table 1.

**CHEMICAL FORMULAS**

Indium In 111 Chloride Sterile Solution contains not less than 95% of the Indium present as ionic In3+. The solutions of Indium In 111 Chloride Sterile Solution contain extremely low levels of these metals. The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained at all times.

**SPECIAL STORAGE AND HANDLING**

**ADVERSE EVENTS**

The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained. Store at controlled room temperature 20-25°C (68-77°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.

**CONTRAINDICATIONS**

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

**INDICATIONS AND USAGE**

Indium In 111 Chloride Sterile Solution is indicated for radiolabeling OncoScint CR/OV or 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 OncoScint CR/OV, ProstaScint or Zevalin for information on the final drug product.

**CONTRAINDICATIONS**

Please refer to the package insert for OncoScint CR/OV, 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 ONCOSEINT CR/OV OR 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 and Impaired Fertility

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

**Pregnancy Category**

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

**Nursing Mothers**

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

**Pediatric Use**

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

**ADVERSE REACTIONS**

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

**DOSAGE AND ADMINISTRATION AND RADIATION DOSIMETRY**

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

**HOW SUPPLIED**

Indium In 111 Chloride Sterile Solution is supplied in 3 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 at time of calibration. The pH of the solution is 1.1 to 1.4.

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**Table 1. Principal Radiation Emission Data**

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean Percent Per Disintegration</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>90.2</td>
<td>171.3</td>
</tr>
<tr>
<td>Gamma-3</td>
<td>94.0</td>
<td>249.4</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Shield Thickness (Pb) cm</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.023</td>
<td>0.5</td>
</tr>
<tr>
<td>0.203</td>
<td>10°</td>
</tr>
<tr>
<td>0.513</td>
<td>10°</td>
</tr>
<tr>
<td>0.824</td>
<td>10°</td>
</tr>
<tr>
<td>1.12</td>
<td>10°</td>
</tr>
</tbody>
</table>

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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; Time-47.32 hours (2.81 days)**

<table>
<thead>
<tr>
<th>Half-life</th>
<th>Hours</th>
<th>Fraction Remaining</th>
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</thead>
<tbody>
<tr>
<td>2.81</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>2.81</td>
<td>6</td>
<td>1.04</td>
</tr>
<tr>
<td>2.81</td>
<td>12</td>
<td>1.08</td>
</tr>
<tr>
<td>2.81</td>
<td>24</td>
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<td>2.81</td>
<td>36</td>
<td>0.69</td>
</tr>
<tr>
<td>2.81</td>
<td>48</td>
<td>0.61</td>
</tr>
<tr>
<td>2.81</td>
<td>72</td>
<td>0.48</td>
</tr>
</tbody>
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