**Cystografin®**

**Diatrizoate Meglumine Injection USP 30%**

For retrograde cystourethrography

Not intended for intravascular injection

**DESCRIPTION**

Cystografin is a radiopaque contrast agent supplied as a sterile, clear, colorless to pale yellow, mobile or slightly viscous solution. Each mL provides 300 mg diatrizoate meglumine with 0.4 mg edetate disodium as a sequestering agent. Each mL of solution also contains approximately 141 mg organically bound iodine. At the time of manufacture, the air in the container is replaced by nitrogen. The preparation should be protected from strong light.

**INDICATION**

Cystografin is indicated for retrograde cystourethrography.

**CONTRAINDICATIONS**

This preparation is contraindicated in patients with a hypersensitivity to salts of diatrizoic acid.

**WARNINGS**

Severe sensitivity reactions are more likely to occur in patients with a personal or family history of bronchial asthma, significant allergies, or previous reactions to contrast agents. A history of sensitivity to iodine per se or to other contrast agents is not an absolute contraindication to the use of diatrizoate meglumine, but calls for extreme caution in administration.

**PRECAUTIONS**

Safe and effective use of this preparation depends upon proper dosage, correct technique, adequate precautions, and readiness for emergencies.

Retrograde cystourethrography should be performed with caution in patients with a known active infectious process of the urinary tract. Sterile technique should be employed in administration. During administration, care should be taken to avoid excessive pressure, rapid or acute distention of the bladder, and trauma. Contrast agents may interfere with some chemical determinations made on urine specimens; therefore, urine should be collected before administration of the contrast medium.

**ADVERSE REACTIONS**

Retrograde genitourinary procedures may cause such complications as hematuria, perforation of the urethra or bladder, introduction of infection into the genitourinary tract, and oliguria or anuria.

**HOW SUPPLIED**

Dilution Table

<table>
<thead>
<tr>
<th>Volume</th>
<th>Water %</th>
<th>Iodine w/v</th>
<th>Organically Bound Iodine w/v</th>
<th>Diatrizoate Meglumine w/v</th>
<th>Total Volume</th>
<th>Final %</th>
<th>Added Sterile Saline</th>
<th>Added Diatrizoate Meglumine</th>
<th>Added Sterile Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 mL</td>
<td>30.0</td>
<td>14.1</td>
<td>100 mL</td>
<td>0.0</td>
<td>0 mL</td>
<td>30.0</td>
<td>14.1</td>
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</tr>
<tr>
<td>25 mL</td>
<td>24.0</td>
<td>11.3</td>
<td>125 mL</td>
<td>0.0</td>
<td>25 mL</td>
<td>24.0</td>
<td>11.3</td>
<td>0.0</td>
<td>50 mL</td>
</tr>
<tr>
<td>50 mL</td>
<td>20.0</td>
<td>9.4</td>
<td>150 mL</td>
<td>0.0</td>
<td>50 mL</td>
<td>20.0</td>
<td>9.4</td>
<td>0.0</td>
<td>75 mL</td>
</tr>
<tr>
<td>67 mL</td>
<td>18.0</td>
<td>8.5</td>
<td>167 mL</td>
<td>0.0</td>
<td>67 mL</td>
<td>18.0</td>
<td>8.5</td>
<td>0.0</td>
<td>95 mL</td>
</tr>
<tr>
<td>300 mL</td>
<td>30.0</td>
<td>14.1</td>
<td>300 mL</td>
<td>0.0</td>
<td>300 mL</td>
<td>30.0</td>
<td>14.1</td>
<td>0.0</td>
<td>330 mL</td>
</tr>
<tr>
<td>50 mL</td>
<td>25.7</td>
<td>12.1</td>
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<td>25.7</td>
<td>12.1</td>
<td>0.0</td>
<td>75 mL</td>
</tr>
</tbody>
</table>

**WARNINGS**

- **YELLOWISH COLOR**: Almost all contrast media are yellowish. A yellowish color in the skin does not indicate a severe reaction.
- **URINARY TRACT**: Cystografin is not intended for intravascular injection. The use of this product is limited to retrograde genitourinary procedures. The commonly employed radiographic technique is retrograde voiding cystourethrography. Prior to the examination, the bladder should be emptied, and the patient instructed to void immediately. A scout film is recommended before the contrast agent is administered. A history of allergy is not an absolute contraindication to the use of Cystografin, but calls for extreme caution in administration.

**INDICATION**

Cystografin (Diatrizoate Meglumine Injection USP 30%) is suitable for intravenous injection in examinations of the urinary tract. It is also suitable for dilution with sterile water or sterile saline, and for intramuscular injection. There are no contraindications to the use of Cystografin in patients with severe renal failure, since it is excreted by the kidneys. It is not indicated for use in pregnant women or in those with a known sensitivity to iodine. Cystografin is recommended for use in the following procedures:

- **CONTRAINDICATIONS**: Cystografin is contraindicated in patients with a known allergic or idiosyncratic reaction to iodine. The presence of bladder discomfort or reflux and/or spontaneous voiding usually indicates that the bladder is full. A sterile catheter should be inserted. The bladder should be filled to capacity with Cystografin using a suitable sterile administration set. Care should be taken to avoid using excessive pressure. The presence of bladder discomfort or reflux and/or spontaneous voiding usually indicates that the bladder is full.

- **Radiography**: The commonly employed radiographic techniques should be used. A scout film is recommended before the contrast agent is administered.