**CYSTOGRAFIN- diatrizoate meglumine injection, solution**
**BRACCO DIAGNOSTICS INC**

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**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 or two or more days afterwards.

**Pregnancy—Teratogenic Effects:**

Animal reproduction studies have not been conducted with diatrizoate meglumine injection. It is also not known whether diatrizoate meglumine injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Cystografin should be administered to a pregnant woman only if clearly needed.

## 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.

If intravasation of this drug occurs, the reactions which may be associated with intravenous administration may possibly be encountered. Hypersensitivity or anaphylactoid reactions may occur. Severe reactions may be manifested by edema of the face and glottis, respiratory distress, convulsions or shock; such reactions may prove fatal unless promptly controlled by such emergency measures as maintenance of a clear airway and immediate use of oxygen and resuscitative drugs.

*Endocrine:* Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and pediatric patients, including infants. Some patients were treated for hypothyroidism.

## DOSAGE AND ADMINISTRATION

**Preparation of the patient:** Appropriate preparation is desirable for optimal results. A laxative the night before the examination and a low residue diet the day before the procedure are recommended.

**Dosage:** The dose for retrograde use in cystography and voiding cystourethrography ranges from 25 to

300 mL depending on the age of the patient and the degree of bladder irritability; amounts greater than 300 mL may be used if the bladder capacity allows. Best results are obtained when the bladder is filled with the contrast agent. If desired, the preparation may be diluted with sterile water or sterile saline as indicated in the table below.

**Administration:** After sterile catheterization, 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.

**Dilution Table**

| **USE DILUTED SOLUTIONS IMMEDIATELY** | | | |
|---|---|---|---|
| **100 mL Bottle** | | | |
| Sterile Water or Sterile Saline Added | % Diatrizoate Meglumine w/v | % Organically Bound Iodine w/v | Total Volume |
| 0 mL | 30.0 | 14.1 | 100 mL |
| 25 mL | 24.0 | 11.3 | 125 mL |
| 50 mL | 20.0 | 9.4 | 150 mL |
| 67 mL | 18.0 | 8.5 | 167 mL |
| **300 mL Bottle** | | | |
| Sterile Water or Sterile Saline Added | | | |
| 0 mL | 30.0 | 14.1 | 300 mL |
| 50 mL | 25.7 | 12.1 | 350 mL |

**HOW SUPPLIED**

Cystografin (Diatrizoate Meglumine Injection USP 30%) is available in 200 mL and 400 mL bottles containing 100 mL and 300 mL of Cystografin respectively with sufficient capacity for dilution up to 167 mL and 350 mL respectively.

**Storage**

Store at 20-25°C (68-77°F) [See USP]. Protect from light.

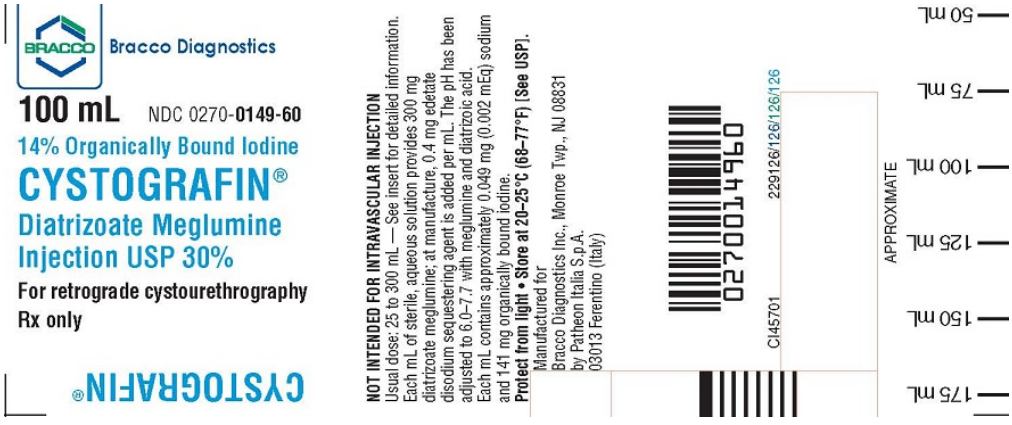
**Also Available**

Cystografin Dilute (Diatrizoate Meglumine Injection USP 18%) is also available, as a 300 mL fill in a 400 mL bottle.

**Rx only**
Manufactured for
**Bracco Diagnostics Inc.**
Monroe Township, NJ 08831
by Patheon Italia S.p.A.
03013 Ferentino (Italy)

Revised April 2018

Cystografin 100 mL Label
NDC 0270-0149-60




**CYSTOGRAFIN**

diatrizoate meglumine injection, solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0270-0149 |
| **Route of Administration** | INTRAVENOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **diatrizoate meglumine** (UNII: 3X9MR4N98U) (diatrizoic acid - UNII:5UVC90J1LK) | diatrizoate meglumine | 300 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **edetate disodium** (UNII: 7FLD91C86K) | 0.4 mg in 1 mL |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0270-0149-60 | 10 in 1 PACKAGE | 11/03/1970 | |
| **1** | | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:0270-0149-57 | 10 in 1 PACKAGE | 11/03/1970 | |
| **2** | | 300 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|---|---|---|---|
| **Marketing Category** | **Application Number or Monograph Citation** | **Marketing Start Date** | **Marketing End Date** |
| NDA | NDA010040 | 11/03/1970 | |

**Labeler -** BRACCO DIAGNOSTICS INC (849234661)

**Registrant -** BRACCO DIAGNOSTICS INC (849234661)

| Establishment | | | |
|---|---|---|---|
| **Name** | **Address** | **ID/FEI** | **Business Operations** |
| PATHEON ITALIA SPA | | 434078638 | MANUFACTURE(0270-0149) , ANALYSIS(0270-0149) |

| Establishment | | | |
|---|---|---|---|
| **Name** | **Address** | **ID/FEI** | **Business Operations** |
| Justesa Imagen, S.A.U | | 477020325 | API MANUFACTURE(0270-0149) |

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