CYSTOGRAFIN DILUTE- diatrizoate meglumine injection, solution
BRACCO DIAGNOSTICS INC

CYSTOGRAFIN® DILUTE
Diatrizoate Meglumine
Injection USP 18%

For retrograde cystourethrography

Not intended for intravascular injection

DESCRIPTION

Cystografin Dilute (Diatrizoate Meglumine Injection USP 18%) is a radiopaque contrast agent supplied as a sterile, aqueous solution. Each mL provides 180 mg diatrizoate meglumine with 0.4 mg edetate disodium as a sequestering agent. Each mL of solution also contains approximately 85 mg organically bound iodine. At the time of manufacture, the air in the container is replaced by nitrogen.

INDICATION

Cystografin Dilute 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 Dilute 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.

Administration: After sterile catheterization, the bladder should be filled to capacity with Cystografin Dilute 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.

HOW SUPPLIED

Cystografin Dilute (Diatrizoate Meglumine Injection USP 18%) is available in packages of ten 300 mL bottIes (NDC 0270-1410-30).

Storage

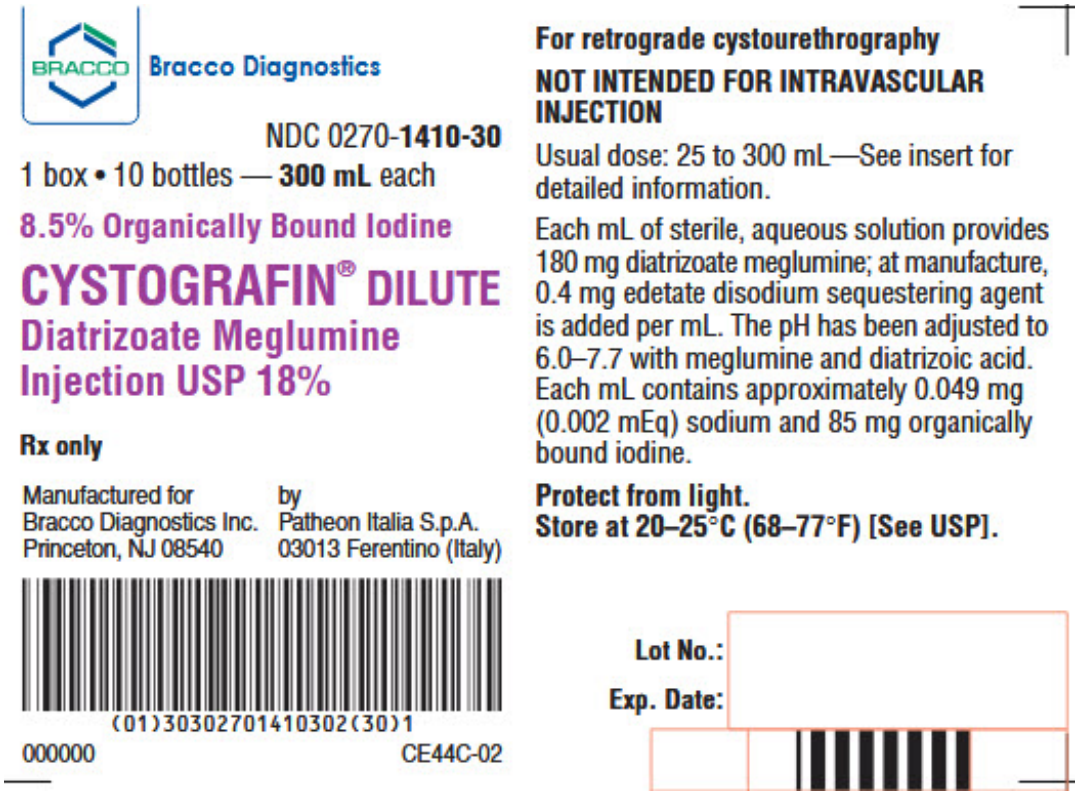
Store at 20-25°C (68-77°F) [See USP]; protect from light.

Rx only
Manufactured for
Bracco Diagnostics Inc.
Princeton, NJ 08540
by Patheon Italia S.p.A.
03013 Ferentino (Italy)

Revised June 2024

CYSTOGRAFIN DILUTE 18% - 300ML
NDC 0270-1410-30

CYSTOGRAFIN DILUTE 18% 1 Box - 10 BTL x 300ML
NDC 0270-1410-30



CYSTOGRAFIN DILUTE

diatrizoate meglumine injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0270-1410
Route of Administration	INTRAVESICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
diatrizoate meglumine (UNII: 3X9MR4N98U) (diatrizoic acid - UNII:5UVC90J1LK)	diatrizoate meglumine	180 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:0270-1410-30	10 in 1 PACKAGE	11/09/1982	
1		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	11/09/1982	

Labeler - BRACCO DIAGNOSTICS INC (849234661)

Registrant - BRACCO DIAGNOSTICS INC (849234661)

Establishment

Name	Address	ID/FEI	Business Operations
PATHEON ITALIA SPA		434078638	ANALYSIS(0270-1410) , MANUFACTURE(0270-1410)

Establishment

Name	Address	ID/FEI	Business Operations
Justesa Imagen, S.A.U		477020325	API MANUFACTURE(0270-1410)

Revised: 11/2025 BRACCO DIAGNOSTICS INC