

ACETIC ACID- acetic acid irrigant
Baxter Healthcare Corporation

0.25% Acetic Acid Irrigation, USP
in Plastic Pour Bottle

DESCRIPTION

0.25% Acetic Acid Irrigation, USP, is a sterile, nonpyrogenic hypotonic solution for irrigation of the urinary bladder. Each 100 mL contains 250 mg Glacial Acetic Acid, USP, (CH₃COOH) in Water for Injection, USP. pH 3.0 (2.8 to 3.4). Osmolarity: 42 mOsmol/L (calc.). No antimicrobial agent has been added.

The container is made from specially formulated polyolefin (PL 325). The polyolefin is a copolymer of ethylene and propylene. It contains no plasticizers or other mobile additives. As a result, the container has virtually no extractability or leachability. The total extractables after two years of storage being less than 0.01 ppm. It is also relatively impermeable to water vapor transmission and, therefore, requires no vapor barrier to maintain the proper drug concentration.

CLINICAL PHARMACOLOGY

The minimal amount of acetic acid which may enter the systemic circulation is readily metabolized.

INDICATIONS AND USAGE

0.25% Acetic Acid Irrigation, USP, is indicated as a constant or intermittent bladder rinse to help prevent the growth and proliferation of susceptible urinary pathogens (especially ammonia forming bacteria) in the management of patients who require prolonged placement of an indwelling urethral catheter. It also may be used for periodic irrigation of an indwelling catheter to help maintain patency by reducing the formation of calcium encrustations.

CONTRAINDICATIONS

None known

WARNINGS

Not for injection.

Use of this solution in patients with mucosal lesions of the urinary bladder may be harmful due to irritation of the lesion. Absorption via open lesions of the bladder mucosa may result in systemic acidosis.

The contents of an opened container should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard the unused portion of irrigating

solution since no antimicrobial agent has been added.

PRECAUTIONS

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with 0.25% Acetic Acid Irrigation, USP. It is also not known whether 0.25% Acetic Acid Irrigation, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.25% Acetic Acid Irrigation, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Warm in oven to not more than 50°C for a maximum of 60 days. Discard after 60 days of warming.

Do not administer unless the solution is clear and the seal is intact.

ADVERSE REACTIONS

Systemic acidosis, pain and hematuria have been reported in patients receiving urinary bladder irrigation with 0.25% Acetic Acid Irrigation, USP.

Should adverse reactions occur, discontinue the irrigation and reevaluate the clinical status of the patient.

DOSAGE AND ADMINISTRATION

The volume of solution needed will vary with nature and duration of the urologic procedure, according to physician's instructions.

Irrigation drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

HOW SUPPLIED

0.25% Acetic Acid Irrigation, USP is supplied in a plastic pour bottle as follows:

2F7184

1000 mL

NDC 0338-0656-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended that the product be stored at room temperature (25°C): brief exposure up to 40°C does not adversely affect the product.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

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07-19-00-0228

Rev. February 2018

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

Not for Injection

2F7184

NDC 0338-0656-04

0.25% Acetic Acid Irrigation, USP

1000 mL

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Bar Code Position Only*

(01) 00303380656042

Baxter

PL 325 plastic

FPO

(91)0709000251

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Made in USA

LOT
EXP

07-09-00-0251

Container Label

Not for Injection 2F7184

NDC 0338-0656-04

**0.25% Acetic Acid
Irrigation, USP**

1000 mL

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PL 325 plastic

Baxter Logo

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Bar Code

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(01) 00303380656042

ACETIC ACID			
acetic acid irrigant			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0656
Route of Administration	IRRIGATION		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETIC ACID (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)		ACETIC ACID	250 mg in 100 mL
Inactive Ingredients			
Ingredient Name		Strength	
WATER (UNII: 059QF0KO0R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0656-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/19/1982	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018523	02/19/1982	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		001728059	MANUFACTURE(0338-0656) , ANALYSIS(0338-0656) , PACK(0338-0656) , LABEL(0338-0656) , STERILIZE(0338-0656)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0656)

Revised: 2/2018

Baxter Healthcare Corporation