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#### Directions for Use of Flexible Plastic Irrigation Containers

If desired, warm in overwrap to near body temperature in a water bath or oven heated to not more than 45°C.

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

## **DIRECTIONS FOR USE**

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired.

Use Aseptic Technique.

- 1. Suspend container using hanger hole.
- 2. Remove plastic protector from outlet port at bottom of container.
- 3. Attach irrigation set. Refer to complete directions accompanying set.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended 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 Mexico

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### PRINCIPAL DISPLAY PANEL - PACKAGING LABELING



3000 mL 2B77127 NDC 0338-0047-47

#### NOT FOR INJECTION

0.9% SODIUM CHLORIDE Irrigation USP

Each 100 mL contains 900 mg Sodium Chloride USP No antimicrobial agent has been added pH 5.5 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolarity 308 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container

Do not use unless solution is clear Discard unused portion

Cautions Squeeze and inspect inner bag

which maintains product sterility Discard if leaks are found **Rx Only** Store unit in moisture barrier overwrap at room temperature (25°C) until ready to use Avoid excessive heat See insert

0.9%

Sodium Chloride NaCl Irrigation USP

**UROMATIC** container

PL 146 plastic

BAXTER UROMATIC and PL 146 are trademarks of Baxter International Inc

For product information 1-800-933-0303

Baxter Logo Baxter Healthcare Corporation Deerfield, IL 60015 USA

Made in Mexico

2700

2400

2100

1800

1500

1200

900

600

000

300

<b>SODIUM CHLORIDE</b> sodium chloride irrigant					
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0047		
Route of Administration	IRRIGATION				
Active Increasing to Mainty					
Active Ingredient/Active	Μοιετλ				
	wedlant Name	Basis o	f Chuchath		

		ingreuient ivaine		Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0 CHLORIDE ION - UNII:Q32ZN48698)			4M0NH37,	SODIUM 900 mg CHLORIDE in 100	
_					
Ir	nactive Ingre			Church	
w	ater (UNII: 059QF			Strei	igth
P	ackaging				
#	ltem Code	Package Description	Marketing Date		rketing End Date
1	NDC:0338-0047- 44	14 in 1 CARTON	05/30/1980		
1		1000 mL in 1 BAG; Type 0: Not a Combination Product			
2	NDC:0338-0047- 46	6 in 1 CARTON	05/30/1980		
2		2000 mL in 1 BAG; Type 0: Not a Combination Product			
3	NDC:0338-0047- 47	4 in 1 CARTON	05/30/1980		
3		3000 mL in 1 BAG; Type 0: Not a Combination Product			
Μ	-	Information			
	Marketing Category	Application Number or Monograph Citation	Marketin Dat		arketing End Date

Labeler - Baxter Healthcare Corporation (005083209)

Establishment				
Name	Address	ID/FEI	Business Operations	
Baxter Healthcare Corporation		059140764	ANALYSIS(0338-0047), LABEL(0338-0047), MANUFACTURE(0338-0047), PACK(0338-0047), STERILIZE(0338-0047)	
Establishment				

Name	Address	ID/FEI	<b>Business Operations</b>
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0047)

# Establishment

Name	Address	ID/FEI	Business Operations
Baxter, S.A. de C.V.		810432484	ANALYSIS(0338-0047), MANUFACTURE(0338-0047), LABEL(0338-0047), PACK(0338-0047), STERILIZE(0338-0047)