

SODIUM CHLORIDE- sodium chloride irrigant
Baxter Healthcare Company

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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88-80-31-833

PRINCIPAL DISPLAY PANEL - PACKAGING LABELING



3000 mL

2B7127

NDC 0338-0047-47

2700

NOT FOR INJECTION



2400

2100

1800

EACH 100mL 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 mOsmo/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER

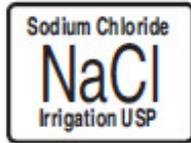
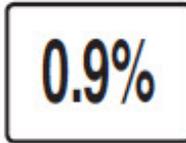
1500

DO NOT USE UNLESS SOLUTION IS CLEAR. DISCARD UNUSED PORTION

1200

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

900



600

UROMATIC CONTAINER

PL 146 PLASTIC

BAXTER UROMATIC AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION 1-800-933-0303

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD, IL 60015 USA
MADE IN MEXICO

300

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 mOsmo/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

300

SODIUM CHLORIDE

sodium chloride irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0047
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Route of Administration	IRRIGATION
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Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength
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Ingredient Name		Strength	Strength	
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)		SODIUM CHLORIDE	900 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:0338-0047-44	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		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA017867	05/30/1980		

Labeler - Baxter Healthcare Company (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	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0047)

Revised: 5/2017

Baxter Healthcare Company