

SODIUM CHLORIDE- sodium chloride irrigant
Baxter Healthcare Corporation

DESCRIPTION

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). Osmolarity 308 mOsmol/L (calc.). Sterile, nonpyrogenic. Pour Bottle.

INDICATIONS AND USAGE

Isotonic solution for irrigation only. Not for injection.

DOSAGE AND ADMINISTRATION

As directed by a physician.

Cautions: Warm in oven to not more than 50°C for a maximum of 60 days. Discard after 60 days of warming. Do not use unless solution is clear and seal is intact. Discard unused portion. Rx only.

HOW SUPPLIED

Recommended storage: Room temperature (25°C). Avoid excessive heat.

PRINCIPAL DISPLAY PANEL - PACKAGING LABELING

2F7124
NDC 0338-0048-04

1000 mL

Baxter

Not for Injection

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Irrigation, USP**

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Bar Code Position Only*

303380048045

FPO

(91)0709000243

PL 325 plastic

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in USA

LOT
EXP

07-09-00-0243

Container Label

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2F7124
NDC 0338-0048-04

1000 mL

Baxter Logo

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SODIUM CHLORIDE

sodium chloride irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0048
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of 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:0338-0048-02	24 in 1 CARTON	12/31/1974	
1		250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0338-0048-03	18 in 1 CARTON	12/31/1974	
2		500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0338-0048-04	12 in 1 CARTON	12/31/1974	

3		1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0338-0048-05	9 in 1 CARTON	12/31/1974	10/31/2022
4		1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017427	12/31/1974	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		001728059	ANALYSIS(0338-0048) , MANUFACTURE(0338-0048) , LABEL(0338-0048) , PACK(0338-0048) , STERILIZE(0338-0048)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0048)

Revised: 2/2014

Baxter Healthcare Corporation