SODIUM CHLORIDE- sodium chloride irrigant
Baxter Healthcare Corporation

0.9% Sodium Chloride Irrigation, USP
in ARTHROMATIC Plastic Container

DESCRIPTION

0.9% Sodium Chloride Irrigation, USP is a sterile nonpyrogenic, isotonic solution in a single dose ARTHROMATIC plastic container for use as an arthroscopic irrigating solution. Each liter contains 9 g Sodium Chloride, USP (NaCl) in Water for Injection. pH 5.5 (4.5 to 7.0). Milliequivalents per liter: Sodium - 154, Chloride - 154. Osmolarity 308 mOsmol/L (calc.). No antimicrobial agent has been added.

The ARTHROMATIC plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexylphthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

0.9% Sodium Chloride Irrigation, USP is useful as an irrigating fluid for body joints because the solution is isotonic, and provides a transparent fluid medium with optical properties suitable for good visualization of the interior joint surface during endoscopic examination. During arthroscopic surgical procedures, the solution acts as a lavage for removing blood, tissue fragments, and bone fragments.

INDICATIONS AND USAGE

0.9% Sodium Chloride Irrigation, USP is indicated for use as an arthroscopic irrigating fluid with endoscopic instruments during arthroscopic procedures requiring distension and irrigation of the knee, shoulder, elbow, or other bone joints.

CONTRAINDICATIONS

None known.

WARNINGS

Not for injection.

Because fluids used to irrigate joints may be absorbed into the general circulation, solutions containing sodium ion should be used with great care in patients with

congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

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

Because some of the fluid used to irrigate joints may be absorbed, caution must be exercised in the volume of irrigating fluid used especially with solutions containing the sodium ion in patients receiving corticosteroids or corticotropin.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

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

ADVERSE REACTIONS

None known.

DOSAGE AND ADMINISTRATION

The volume of solution needed will vary with the nature and duration of the arthroscopic procedure.

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

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

HOW SUPPLIED

0.9% Sodium Chloride Irrigation, USP in ARTHROMATIC Plastic Container is available as follows:

2B7477	3000 mL	NDC 0338-0047-27
2B7479	5000 mL	NDC 0338-0047-29

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

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 protector from outlet port.
3. Attach irrigation set. Refer to complete directions accompanying set.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

07-19-00-0407
Rev. July 2018

PACKAGE LABEL.PRINCIPLE DISPLAY PANEL

0.9% Sodium Chloride Irrigation USP Container Label

0.9% Sodium Chloride Irrigation USP Container Label

NOT FOR INJECTION

5000 mL

2B7479

NDC 0338-0047-29

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
ARTHROMATIC CONTAINER PL 146 PLASTIC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
BAXTER ARTHROMATIC AND
PL 146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC
FOR PRODUCT INFORMATION
1-800-933-0303

SODIUM CHLORIDE
sodium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0047
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:0338-0047-24	14 in 1 CARTON	05/30/1980	12/22/2012
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0338-0047-27	4 in 1 CARTON	05/30/1980	
2		3000 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:0338-0047-29	2 in 1 CARTON	05/30/1980	
3		5000 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 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	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0047)

Revised: 7/2018 Baxter Healthcare Corporation