SODIUM CHLORIDE- sodium chloride irrigant
Baxter Healthcare Corporation

0.9% Sodium Chloride Irrigation, USP
Baxter Sterile Container System

DESCRIPTION

0.9% Sodium Chloride Irrigation, USP in the Baxter Sterile Container System is a sterile, nonpyrogenic, isotonic solution for the preparation of slushed solution. It contains no antimicrobial agents. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)	Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)	
		Sodium Chloride, USP (NaCl)			Sodium	Chloride
0.9 % Sodium Chloride Irrigation, USP	1000	9	308	5.0 (4.5 to 7.0)	154	154

The Baxter Sterile Container System is designed to provide a slush container with a **sterile exterior surface** for use within the surgical field. Within the overwrap, the unit is packaged in a dispensing bag which maintains the sterility of this surface.

The flexible plastic slush 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-ethylhexyl phthalate (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 culture toxicity studies.

CLINICAL PHARMACOLOGY

Slushed solution is used to induce regional hypothermia in conditions such as certain open heart and kidney surgical procedures by direct application of slushed solution. The objective of regional hypothermia is to reduce cellular metabolic activity so that body tissues can tolerate a period of total or relative ischemia thereby inhibiting the formation and buildup of destructive autolytic enzymes and anaerobic by-products usually produced and accumulated in ischemic tissues.

INDICATIONS AND USAGE

Slushed solution is used to create regional hypothermia in order to reduce and minimize manifestations of warm-temperature ischemia. Temperature probes may be used to determine requirements for replacement or addition of slushed solution.

CONTRAINDICATIONS

None known

WARNINGS

Not for injection. For use in slush preparation for regional hypothermia.

PRECAUTIONS

General Precautions

Avoid prolonged direct contact between ice crystals and body tissues.

Experience in use of slushed solutions in pediatrics is limited.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies performed with slushed 0.9% Sodium Chloride Irrigation, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with slushed 0.9% Sodium Chloride Irrigation, USP. It is also not known whether slushed 0.9% Sodium Chloride Irrigation, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Slushed 0.9% Sodium Chloride Irrigation, USP should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when slushed 0.9% Sodium Chloride Irrigation, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of slushed 0.9% Sodium Chloride Irrigation, USP in pediatric patients have not been established by adequate and well controlled trials; however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Do not administer unless seals of outer dispensing bag are intact.

ADVERSE REACTIONS

No serious adverse reactions are known.

DOSAGE AND ADMINISTRATION

The volume of slushed solution required will vary with patient's age, clinical condition, cooling effect desired and duration of cooling effect desired, according to physician's instructions.

HOW SUPPLIED/STORAGE AND HANDLING

.9% Sodium Chloride Irrigation, USP in the Baxter Sterile Container System is supplied as follows:

Code	Size (mL)	NDC	DIN
2B7231	1000	0338-0051-44	786160

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Avoid freezing except during controlled slushing procedure. It is recommended that this product be stored at room temperature (25ºC); brief exposure up to 40ºC does not adversely affect this product.

DIRECTIONS FOR USE OF THE BAXTER STERILE CONTAINER SYSTEM

Guidelines for Preparation of Slush

The following instructions are intended only as guidelines for the preparation of slush using the Baxter Sterile Container System. The specific procedure necessary to achieve the desired slush consistency will depend on the type of freezer used, location of the product in the freezer, and the utilization of freezer capacity.

1. Remove product from shipping carton and place in freezer at a temperature between minus 4ºC and minus 15ºC for 2 to 6 hours. Note: A pre-cooled product will require less time to slush.
2. During the freezing process, remove product from freezer periodically and carefully massage to break up large frozen chunks of solution.
3. Return product to freezer and repeat procedure until desired slush consistency is obtained.

To Open: Use Aseptic Technique

A. To prepare unit outside the surgical field.

1. Tear overwrap down side at slit and remove dispensing bag which contains the slush container.
2. Allow unit to stand at room temperature for approximately 10 minutes to allow container material to regain flexibility.

3. Check that all the seals of the dispensing bag are intact including the tamper evident button. If any broken seals or holes are detected, discard unit as sterility may be impaired.
4. Grasp tab of dispensing bag and peel open (Figure 1). Remove wrapped inner slush container.
5. Grasp point of sterile transfer wrap (Figure 2), and pull forward then back to expose sterile slush container (Figure 3). Caution should be exercised to avoid touch contamination.

B. To transfer sterile slush container to the surgical field.

1. Using sterile gloved hands, remove slush container from the sterile transfer wrap (Figure 4). Place on surgical field or use immediately.
2. Grasp tab at top of slush container and peel directly across the width of the container with a steady motion (Figure 5).
3. Slush is ready for dispensing.

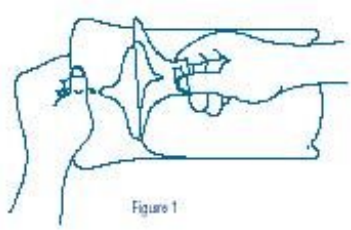
Figure 1


Figure 2

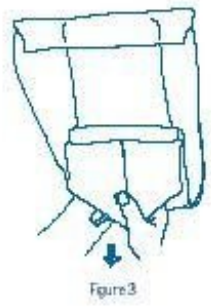
Figure 3

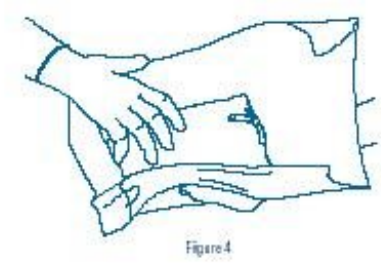

Figure 4

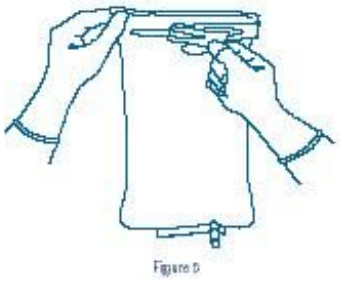

Figure 5

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

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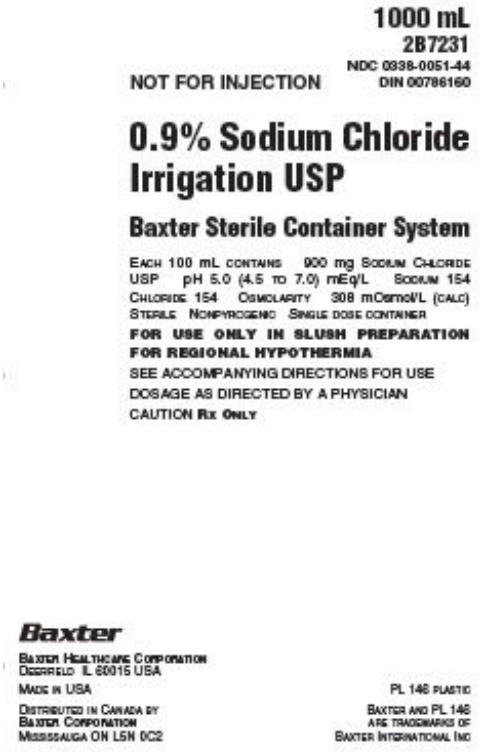
PRINCIPAL DISPLAY PANEL - PACKAGING LABELING



1000 mL
2B7231

NDC 0338-0051-44
Din 00786160

NOT FOR INJECTION

0.9% Sodium Chloride
Irrigation, USP
Baxter Sterile Container System

EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE
USP pH 5.0 (4.5 TO 7.0) mEq/L SODIUM 154
CHLORIDE 154 OSMOLARITY 308 mOsmol/L (CALC)
STERILE NONPYROGENIC SINGLE DOSE CONTAINER

FOR USE ONLY IN SLUSH PREPARATION
FOR REGIONAL HYPOTHERMIA

SEE ACCOMPANYING DIRECTIONS FOR USE
DOSAGE AS DIRECTED BY A PHYSICIAN
CAUTION **RX ONLY**

Baxter Logo
Baxter Healthcare Corporation
Deerfield IL 60015 USA

Made in USA

Distributed in Canada by
Baxter Corporation
Misissauga ON L5N 0C2

PL 146 Plastic

SODIUM CHLORIDE

sodium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0051
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	9 g in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0338-0051-44	1000 mL in 1 BAG; Type 0: Not a Combination Product	05/17/1985	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019319	05/17/1985	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	MANUFACTURE(0338-0051) , ANALYSIS(0338-0051) , PACK(0338-0051) , LABEL(0338-0051) , STERILIZE(0338-0051)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare			ANALYSIS(0338-0051) , MANUFACTURE(0338-0051) , LABEL(0338-0051)

Baxter Healthcare Corporation		189326168	ANALYSIS(0338-0051) , MANUFACTURE(0338-0051) , LABEL(0338-0051) , PACK(0338-0051) , STERILIZE(0338-0051)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0051)