SODIUM CHLORIDE- sodium chloride solution
Baxter Healthcare Corporation

0.9% Sodium Chloride Processing Solution
in Flexible Plastic Container
Not for injection

DESCRIPTION

Sodium Chloride Processing Solution is a sterile, nonpyrogenic solution in single dose container for use in blood cell processing devices. 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 Processing Solution	3000	9	308	5.5 (4.5 to 7.0)	154	154

The 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 Processing Solution has value as a physiological blood cell processing aid.

INDICATIONS AND USAGE

0.9% Sodium Chloride Processing Solution is indicated in processing blood cells.

See directions accompanying blood cell processing device for complete instructions for use.

CONTRAINDICATIONS

None known

WARNINGS

This container should not be connected for direct intravenous administration.

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 processing solution.

PRECAUTIONS

Careful review and understanding of the use of this solution in conjunction with blood cell processing equipment is essential.

Pregnancy

Teratogenic Effects

Pregnancy Category C.

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

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

ADVERSE REACTIONS

None known

DOSAGE AND ADMINISTRATION

As directed by a physician. See directions accompanying blood cell processing device.

Processing Solutions should be inspected visually for particulate matter and discoloration prior to use.

HOW SUPPLIED

0.9% Sodium Chloride Processing Solution in Flexible Plastic Container is available as follows:

Code	Size (mL)	NDC
2B7207	3000	0338-0050-47

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.

To Open

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 inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

Preparation for Use

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach to blood cell processing device. Refer to complete directions accompanying blood cell processing device.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Printed in USA

07-19-73-065

Rev. May 2014

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

3000 mL

2B7207
NDC 0338-0050-47

NOT FOR INJECTION

0.9%
SODIUM CHLORIDE
Processing Solution

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

DOSAGE AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS
ACCOMPANYING BLOOD CELL PROCESSING DEVICE FOR USE THIS
CONTAINER SHOULD NOT BE CONNECTED FOR DIRECT INTRAVENOUS
ADMINISTRATION

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND DO NOT USE UNLESS SOLUTION IS CLEAR DISCARD UNUSED PORTION **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
Processing Solution

VIAFLEX CONTAINER

PL146 PLASTIC
FOR PRODUCT INFORMATION

1-800-933-0303

Baxter Logo
Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in USA

SODIUM CHLORIDE

sodium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0050
Route of Administration	EXTRACORPOREAL		

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:0338-0050-47	4 in 1 CARTON	05/30/1980	
1		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 Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	MANUFACTURE(0338-0050) , STERILIZE(0338-0050) , PACK(0338-0050) , LABEL(0338-0050) , ANALYSIS(0338-0050)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0050)

Revised: 7/2014 Baxter Healthcare Corporation