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

<table>
<thead>
<tr>
<th>Size (mL)</th>
<th>Composition (g/L)</th>
<th>Osmolarity (mOsmol/L) (calc)</th>
<th>pH</th>
<th>Ionic Concentration (mEq/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9% Sodium Chloride Processing Solution</td>
<td>9</td>
<td>308</td>
<td>5.5 (4.5 to 7.0)</td>
<td>154</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Size (mL)</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2B7207</td>
<td>3000</td>
<td>0338-0050-47</td>
</tr>
</tbody>
</table>

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

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Rev. May 2014

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PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

3000 mL

2B7207

0.9% SODIUM CHLORIDE Processing Solution

NOT FOR INJECTION

NDC 0336-0050-47

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 mOsm/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

PL 146 and PL 146 are trademarks of Baxter International Inc.

Made in USA

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

For product information 1-800-993-0030

Baxter, PL 146 and VIAFLEX are trademarks of Baxter International Inc.
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

Baxter VIAFLEX and PL 146 are trademarks of Baxter International Inc
SODIUM CHLORIDE
sodium chloride solution

Product Information

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

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q3Z148698)</td>
<td>SODIUM CHLORIDE</td>
<td>900 mg in 100 mL</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>WATER</td>
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<tr>
<td>(UNII: 059QF0KO0R)</td>
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</tbody>
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### Packaging

<table>
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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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<tbody>
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<td>1</td>
<td>NDC:0338-0050-47</td>
<td>4 in 1 CARTON</td>
<td>05/30/1980</td>
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<tr>
<td>1</td>
<td></td>
<td>3000 mL in 1 BAG; Type 0: Not a Combination Product</td>
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### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>NDA</td>
<td>NDA017867</td>
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### Labeler

Baxter Healthcare Corporation (005083209)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
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<td>Baxter Healthcare Corporation</td>
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<td>059140764</td>
<td>MANUFACTURE(0338-0050), STERILIZE(0338-0050), PACK(0338-0050), LABEL(0338-0050), ANALYSIS(0338-0050)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
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<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare Corporation</td>
<td></td>
<td>194684502</td>
<td>ANALYSIS(0338-0050)</td>
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Revised: 7/2014

Baxter Healthcare Corporation