DEXTROSE AND SODIUM CHLORIDE- dextrose and sodium chloride injection, solution
Baxter Healthcare Corporation

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Dextrose and Sodium Chloride Injection, USP
in VIAFLEX Plastic Container

DESCRIPTION
Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and
electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It
contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content
are shown in 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>
<th>Caloric Content (kcal/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dextrose Hydrous, USP</strong></td>
<td>Sodium Chloride, USP (NaCl)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5% Dextrose and 0.45% Sodium Chloride Injection, USP</td>
<td>500 1000</td>
<td>25</td>
<td>4.5</td>
<td>280</td>
<td>4.5 (3.2 to 6.5)</td>
</tr>
<tr>
<td>5% Dextrose and 0.2% Sodium Chloride Injection, USP</td>
<td>250 500 1000</td>
<td>50</td>
<td>2</td>
<td>321</td>
<td>4.0 (3.2 to 6.5)</td>
</tr>
<tr>
<td>5% Dextrose and 0.33% Sodium Chloride Injection, USP</td>
<td>500</td>
<td>50</td>
<td>3.3</td>
<td>365</td>
<td>4.0 (3.2 to 6.5)</td>
</tr>
<tr>
<td>5% Dextrose and 0.45% Sodium Chloride Injection, USP</td>
<td>250 500 1000</td>
<td>50</td>
<td>4.5</td>
<td>406</td>
<td>4.0 (3.2 to 6.5)</td>
</tr>
<tr>
<td>5%</td>
<td>250 50 9</td>
<td>560</td>
<td>4.0</td>
<td>154</td>
<td>154</td>
</tr>
</tbody>
</table>
Dextrose and Sodium Chloride Injection, USP

500
1000

(3.2 to 6.5)

* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.

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The VIAFLEX 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-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 tissue culture toxicity studies.

**CLINICAL PHARMACOLOGY**

Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

**INDICATIONS AND USAGE**

Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

**CONTRAINDICATIONS**

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

**WARNINGS**

Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.
The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

**PRECAUTIONS**

**General**

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Administration of hypertonic solutions may cause venous irritation, including phlebitis. Hyperosmolar solutions should be administered with caution, if at all, to patients with hyperosmolar states. See Table 1 in the DESCRIPTION section for the osmolarities of the Dextrose and Sodium Chloride Injection, USP solutions.

**Laboratory Tests**

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

**Drug Interaction**

Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Studies with Dextrose and Sodium Chloride Injection, 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 Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, 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 Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

**Pediatric Use**

The Use of Dextrose and Sodium Chloride, USP in pediatric patients is based on clinical practice.

Newborns – especially those born premature and with low birth weight – are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency (applies to solutions containing less than 0.9% sodium chloride).

**Geriatric Use**

Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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

**ADVERSE REACTIONS**

- Anaphylactic reaction, hypersensitivity, and chills
- Hyponatremia (applies to solutions containing less than 0.9% Sodium Chloride)

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

**DOSAGE AND ADMINISTRATION**

As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

The dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of
hyperglycemia/hypoglycemia. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

Additives may be incompatible. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

**HOW SUPPLIED**

Dextrose and Sodium Chloride Injection, USP in VIAFLEX plastic container is supplied as follows:

<table>
<thead>
<tr>
<th>Code</th>
<th>Size (mL)</th>
<th>NDC</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2B1024</td>
<td>1000</td>
<td>0338-0073-04</td>
<td>2.5% Dextrose and 0.45% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1092</td>
<td>250</td>
<td>0338-0077-02</td>
<td>5% Dextrose and 0.2% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1093</td>
<td>500</td>
<td>0338-0077-03</td>
<td>Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1094</td>
<td>1000</td>
<td>0338-0077-04</td>
<td></td>
</tr>
<tr>
<td>2B1083</td>
<td>500</td>
<td>0338-0081-03</td>
<td>5% Dextrose and 0.33% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1073</td>
<td>500</td>
<td>0338-0085-03</td>
<td>5% Dextrose and 0.45% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1074</td>
<td>1000</td>
<td>0338-0085-04</td>
<td>Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1063</td>
<td>500</td>
<td>0338-0089-03</td>
<td>5% Dextrose and 0.9% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>2B1064</td>
<td>1000</td>
<td>0338-0089-04</td>
<td>Sodium Chloride Injection, USP</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 (25°C); brief exposure up to 40°C does not adversely affect the product.

**DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER**

**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. If supplemental medication is desired, follow directions below.

**Preparation for Administration**

- Suspend container from eyelet support.
- Remove plastic protector from outlet port at bottom of container.
- Attach administration set. Refer to complete directions accompanying set.
To Add Medication

WARNING
Additives may be incompatible.

To add medication before solution administration

- Prepare medication site.
- Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
- Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

- Close clamp on the set.
- Prepare medication site.
- Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
- Remove container from IV pole and/or turn to an upright position.
- Evacuate both ports by squeezing them while container is in the upright position.
- Mix solution and medication thoroughly.
- Return container to in use position and continue administration.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

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PACKAGE LABELING - PRINCIPAL DISPLAY PANEL
5% Dextrose and 0.9% Sodium Chloride Injection USP

500 mL

Each 100 mL contains 5 g Dextrose Hydrous USP 900 mg Sodium Chloride USP pH 4.0 (3.2 to 6.5) mEq/L Sodium 154 Chloride 154 Hypertonic Osmolarity 560 mOsmol/L (Calc) Sterile Nonpyrogenic Single dose container Additives may be incompatible Consult with pharmacist if available When introducing additives use aseptic technique Mix thoroughly Do not store Dosage Intravenously as directed by a physician See directions Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Must not be used in series connections Do not use unless solution is clear Rx Only Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use Avoid excessive heat See insert

Viaflex container PL 146 plastic

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For product information 1-800-933-0303

Baxter Healthcare Corporation
Deerfield IL 60015 USA
Made in USA
5% Dextrose and
0.9% Sodium Chloride
Injection USP

500 mL EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP
900 mg SODIUM CHLORIDE USP pH 4.0 (3.2 TO 6.5)
mEq/L SODIUM 154 CHLORIDE 154 HYPERTONIC
OSMOLARITY 560 mOsmol/L (CALC) STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE
WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS
DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS
SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT
STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED
IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS
CLEAR RX ONLY STORE UNIT IN MOISTURE BARRIER
OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY
TO USE AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX CONTAINER PL 146 PLASTIC
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BAXTER INTERNATIONAL INC
FOR PRODUCT INFORMATION 1-800-933-0303

BAXTER Logo
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA
2B1063Q 24-500 ML

VIAFLEX® CONTAINER

5% DEXTROSE AND
0.9% SODIUM CHLORIDE INJ, USP

Carton Label
2B1063Q 24-500 ML
VIAFLEX® CONTAINER
5% DEXTROSE AND
0.9% SODIUM CHLORIDE INJ, USP
EXP
XXXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT
XXXXXX
PRIMARY BAR CODE
(01) 50303380089036
2.5% Dextrose and 0.45% Sodium Chloride Injection USP

1000 mL

Each 100 mL contains 2.5 g Dextrose Hydrous USP, 450 mg Sodium Chloride USP, pH 4.5 (3.2 to 6.5) mEq/L Sodium 77 Chloride 77 Osmolarity 280 mOsmol/L (calc). Sterile, Nonpyrogenic, Single dose container. Additives may be incompatible. Consult with pharmacist if available. When introducing additives use aseptic technique. Mix thoroughly. Do not store Dosage Intravenously as directed by a physician. See directions. Cautions. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Must not be used in series connections. Do not use unless solution is clear. Rx Only. Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use. Avoid excessive heat. See insert.

VIAFLEX container PL 146 plastic

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For product information 1-800-933-0303

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA
Container Label

LOT EXP

2B1024
NDC 0338-0073-04

2.5% Dextrose
and 0.45%
Sodium Chloride
Injection USP

1000 mL

EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
450 mg SODIUM CHLORIDE USP pH 4.0 (3.2 TO 6.5)
mEq/L SODIUM 77 CHLORIDE 77 OSMOLARITY 280
mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE
DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE
CONSULT WITH PHARMACIST IF AVAILABLE WHEN
INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY
AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS
SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS
PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST
NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS
SOLUTION IS CLEAR RX ONLY STORE UNIT IN MOISTURE
BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F)
UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX CONTAINER PL 146 PLASTIC

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FOR PRODUCT INFORMATION 1-800-933-0303

Baxter Logo

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
2B1024X 14-1000 ML
VIAFLEX® CONTAINER
2.5% DEXTROSE AND
0.45% SODIUM CHLORIDE INJ, USP

EXP
XXXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX

LOT
XXXXXX
PRIMARY BAR CODE
(01) 50303380073042
Container Label

LOT EXP
2B1092
NDC 0338-0077-02

5% Dextrose and
0.2% Sodium Chloride
Injection USP

250 mL EACH 100 mL CONTAINS
5 g DEXTROSE HYDROUS
USP 200 mg SODIUM CHLORIDE USP
pH 4.0 (3.2 TO 6.5) mEq/L SODIUM 34
Osmolarity 321 mOsmol/L
(calc) STERILE NONPYOGENIC SINGLE
DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE. CONSULT WITH PHARMACIST
IF AVAILABLE. WHEN INTRODUCING ADDITIVES
USE ASEPTIC TECHNIQUE. MIX THOROUGHLY.
DO NOT STORE. DOSAGE INTRAVENOUSLY AS
DIRECTED BY A PHYSICIAN. SEE DIRECTIONS
CAUTIONS. SQUEEZE AND INSPECT INNER
BAG WHICH MAINTAINS PRODUCT STERILITY.
DISCARD IF LEAKS ARE FOUND. MUST NOT BE
USED IN SERIES CONNECTIONS. DO NOT
ADMINISTER SIMULTANEOUSLY WITH BLOOD
DO NOT USE UNLESS SOLUTION IS CLEAR. Rx
ONLY. STORE UNIT IN MOISTURE BARRIER
OVERWRAP AT ROOM TEMPERATURE
(25°C/77°F) UNTIL READY TO USE. AVOID
EXCESSIVE HEAT. SEE INSERT.

VIAFLEX CONTAINER PL 146 PLASTIC
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FOR PRODUCT INFORMATION
1-800-933-0303

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

Container Label
CHLORIDE 34 OSMOLARITY 321 mOsmol/L
(CALC) STERILE NONPYROGENIC SINGLE
DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST
IF AVAILABLE WHEN INTRODUCING ADDITIVES
USE ASEPTIC TECHNIQUE MIX THOROUGHLY
DO NOT STORE DOSAGE INTRAVENOUSLY AS
DIRECTED BY A PHYSICIAN SEE DIRECTIONS
CAUTIONS SQUEEZE AND INSPECT INNER
BAG WHICH MAINTAINS PRODUCT STERILITY
DISCARD IF LEAKS ARE FOUND MUST NOT BE
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ONLY STORE UNIT IN MOISTURE BARRIER
OVERWRAP AT ROOM TEMPERATURE
(25°C/77°F) UNTIL READY TO USE AVOID
EXCESSIVE HEAT SEE INSERT
VIAFLEX CONTAINER PL 146 PLASTIC
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TRADEMARKS OF BAXTER INTERNATIONAL INC
FOR PRODUCT INFORMATION
1-800-933-0303

BAXTER Logo
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

50
100
150
200
2B1092Q 36-250 ML
VIAFLEX® CONTAINER

5% DEXTROSE AND
0.2% SODIUM CHLORIDE INJ, USP

EXP
XXXXXX  SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX

LOT
XXXXXX  PRIMARY BAR CODE
(01) 50303380077026

Carton Label

Carton Label
Carton Label
2B1092Q 36-250 ML
VIAFLEX® CONTAINER
5% DEXTROSE AND
0.2% SODIUM CHLORIDE INJ, USP
EXP
XXXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT
XXXXXX
PRIMARY BAR CODE
(01) 50303380077026
5% Dextrose and 0.33% Sodium Chloride Injection USP

500 mL

Each 100 mL contains 5 g Dextrose Hydrous USP
330 mg Sodium Chloride USP pH 4.0 (3.2 to 6.5)
1 mEq/L Sodium 56 Chloride 56 Osmolarity 365
mOsmol/L (calc) Sterile Nonpyrogenic Single dose
container Additives may be incompatible Consult with
pharmacist if available When introducing additives use
aseptic technique Mix thoroughly Do not store
Dosage Intravenously as directed by a physician See
directions Cautions Squeeze and inspect inner bag
which maintains product sterility Discard if leaks are
found Must not be used in series connections Do not
administer simultaneously with blood Do not use
unless solution is clear Rx Only Store unit in
moisture barrier overwrap at room temperature
(25°C/77°F) until ready to use Avoid excessive heat
See insert

VIAFLEX container PL 146 plastic
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For product information 1-800-933-0303

Baxter Healthcare Corporation
DEERFIELD IL 60015 USA
MADE IN USA

07-25-34-096
LOT EXP
2B1083
NDC 0338-0081-03
5% Dextrose and
0.33% Sodium Chloride
Injection USP

500 mL

EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP
330 mg SODIUM CHLORIDE USP pH 4.0 (3.2 TO 6.5)
1 mEq/L SODIUM 56 CHLORIDE 56 OSMOLARITY 356
1 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE

CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH
PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE
ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE

DOSSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE
DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE
FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT
USE UNLESS SOLUTION IS CLEAR RX ONLY STORE UNIT IN
MOISTURE BARRIER OVERWRAP T ROOM TEMPERATURE
(25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT
SEE INSERT

VIAFLEX CONTAINER PL 146 PLASTIC
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FOR PRODUCT INFORMATION 1-800-933-0303

Baxter Logo
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

07-25-34-096

1
2
3
4
2B1083Q 24-500 ML

VIAFLEX® CONTAINER

5% DEXTROSE AND
0.33% SODIUM CHLORIDE INJ, USP

EXP
XXXXXX

SECONDARY BAR CODE
(17) XXXXX (10) XXXXX

LOT
XXXXXX

PRIMARY BAR CODE
(01) 50303380081030

Carton Label

2B1083Q 24-500 ML

VIAFLEX® CONTAINER

5% DEXTROSE AND
0.33% SODIUM CHLORIDE INJ, USP

EXP
XXXXXX

SECONDARY BAR CODE
(17) XXXXX (10) XXXXX

LOT
XXXXXX

PRIMARY BAR CODE
(01) 50303380081030
5% Dextrose and 0.45% Sodium Chloride Injection USP

500 mL

Each 100 mL contains 5 g Dextrose Hydrous USP
450 mg Sodium Chloride USP pH 4.0 (3.2 to 6.5) mEq/L Sodium 77 Chloride 77 Hypertonic Osmolarity
406 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container Additives may be incompatible Consult with pharmacist if available When introducing additives use aseptic technique Mix thoroughly Do not store Dosage intravenously as directed by a physician See directions Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Must not be used in series connections Do not use unless solution is clear Rx Only Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use Avoid excessive heat See insert

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Baxter Healthcare Corporation
Deerfield IL 60015 USA
Made in USA
450 mg SODIUM CHLORIDE USP pH 4.0 (3.2 TO 6.5)

mEq/L SODIUM 77 CHLORIDE 77 HYPERTONIC OSMOLARITY

406 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE

DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES

USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR RX ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX CONTAINER PL 146 PLASTIC

BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION 1-800-933-0303

BAXTER Logo

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

1

2

3

4
Carton Label

2B1073Q 24-500 ML

VIAFLEX® CONTAINER

5% DEXTROSE AND
0.45% SODIUM CHLORIDE INJ, USP

EXX
XXXXXX  SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX

LOT
XXXXXX  PRIMARY BAR CODE
(01) 50303380085038

Carton Label

2B1073Q 24-500 ML

VIAFLEX® CONTAINER

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EXP
XXXXXX

SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX

LOT
XXXXXX

PRIMARY BAR CODE
(01) 50303380085038

DEXTROSE AND SODIUM CHLORIDE
Dextrose and sodium chloride injection, solution

| Product Information |  |
|---------------------|  |
| **Product Type**    | HUMAN PRESCRIPTION DRUG |
| **Item Code (Source)** | NDC:0338-0073 |
### Route of Administration

**INTRAVENOUS**

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>2.5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>450 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

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

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-0073-04</td>
<td>14 in 1 CARTON</td>
<td>03/22/1971</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
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</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA016697</td>
<td>03/22/1971</td>
<td></td>
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</tbody>
</table>

### DEXTROSE AND SODIUM CHLORIDE

dextrose and sodium chloride injection, solution

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0338-0077</td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>200 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

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

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-0077-02</td>
<td>36 in 1 CARTON</td>
<td>12/08/1970</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>250 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0338-0077-03</td>
<td>24 in 1 CARTON</td>
<td>12/08/1970</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0338-0077-04</td>
<td>14 in 1 CARTON</td>
<td>12/08/1970</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
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</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA016689</td>
<td>12/08/1970</td>
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</tbody>
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## DEXTROSE AND SODIUM CHLORIDE
dextrose and sodium chloride injection, solution

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0338-0081</th>
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</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTRAVENOUS</td>
<td></td>
<td></td>
</tr>
</tbody>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X)</td>
<td>SODIUM CHLORIDE</td>
<td>330 mg in 100 mL</td>
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</tbody>
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## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
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<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-0081-02</td>
<td>36 in 1 CARTON</td>
<td>03/22/1971</td>
<td>05/31/2007</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>250 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0338-0081-03</td>
<td>24 in 1 CARTON</td>
<td>03/22/1971</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:0338-0081-04</td>
<td>14 in 1 CARTON</td>
<td>03/22/1971</td>
<td>04/30/2007</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
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</table>
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<tr>
<td>NDA</td>
<td>NDA016687</td>
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**DEXTROSE AND SODIUM CHLORIDE**
dextrose and sodium chloride injection, solution

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<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0338-0085</td>
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**Active Ingredient/Active Moiety**

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<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4MNHB7, CHLORIDE ION - UNII:E32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>450 mg in 100 mL</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

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<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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<tbody>
<tr>
<td>1</td>
<td>NDC:0338-0085-03</td>
<td>24 in 1 CARTON</td>
<td>03/22/1971</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:0338-0085-04</td>
<td>500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>03/22/1971</td>
<td></td>
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<tr>
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<td>NDC:0338-0085-03</td>
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<td>03/22/1971</td>
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<tbody>
<tr>
<td>NDA</td>
<td>NDA016683</td>
<td>03/22/1971</td>
<td></td>
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</tbody>
</table>
### Active Ingredient/Active Moiety

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<tbody>
<tr>
<td>DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7RO0K)</td>
<td>DEXTROSE MONOHYDRATE</td>
<td>5 g in 100 mL</td>
</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)</td>
<td>SODIUM CHLORIDE</td>
<td>900 mg in 100 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

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<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0338-0089-03</td>
<td>24 in 1 CARTON</td>
<td>12/09/1970</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>500 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/09/1970</td>
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</tr>
<tr>
<td>2</td>
<td>NDC:0338-0089-04</td>
<td>14 in 1 CARTON</td>
<td>12/09/1970</td>
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</tr>
<tr>
<td>2</td>
<td></td>
<td>1000 mL in 1 BAG; Type 0: Not a Combination Product</td>
<td>12/09/1970</td>
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</table>

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<tbody>
<tr>
<td>NDA</td>
<td>NDA016678</td>
<td>12/09/1970</td>
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</tbody>
</table>

### Labeler - Baxter Healthcare Corporation (005083209)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare Corporation</td>
<td></td>
<td>059140764</td>
<td>MANUFACTURE(0338-0073, 0338-0077, 0338-0081, 0338-0085, 0338-0089), ANALYSIS(0338-0073, 0338-0077, 0338-0081, 0338-0085, 0338-0089), LABEL(0338-0073, 0338-0077, 0338-0081, 0338-0085, 0338-0089), PACK(0338-0073, 0338-0077, 0338-0081, 0338-0085, 0338-0089), STERILIZE(0338-0073, 0338-0077, 0338-0081, 0338-0085, 0338-0089)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter Healthcare Corporation</td>
<td></td>
<td>194684502</td>
<td>ANALYSIS(0338-0073, 0338-0077, 0338-0081, 0338-0085, 0338-0089)</td>
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</table>

Revised: 2/2018