Dextrose and Sodium Chloride Injection, USP

in AVIVA 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, osmolality, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Composition (g/L)</th>
<th>Sodium Chloride, USP</th>
<th>Caloric Content (kcal/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose Hydrous, USP</td>
<td>100</td>
<td>813</td>
</tr>
<tr>
<td>Sodium Chloride, USP</td>
<td>40</td>
<td>34</td>
</tr>
<tr>
<td>pH</td>
<td>5.5</td>
<td>5.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sodium Chloride, USP</th>
<th>100</th>
<th>900 (3.2 to 6.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>5.5</td>
<td>5.5</td>
</tr>
</tbody>
</table>

Directions for Use: The primary function of the overwrap is to protect the container from the physical environment.

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
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.

Drug Interactions
Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, and impairment of fertility. Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

Precautions
Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a 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.

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

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

Contraindications
Dextrose and Sodium Chloride Injection, USP is contraindicated in patients with known allergy to corn or corn products.

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Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Dextrose and Sodium Chloride Injection, USP.

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.

The flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of pacilaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The stability of the container materials has been established through biological evaluations, which have shown the container passes Class VI USP testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is perfused in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of supplemental medication (See
Pregnancy: Teratogenic Effects
Pregnancy Category C. 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.

Labor and Delivery
Studies have not been conducted to evaluate the effects of Dextrose and Sodium Chloride Injection, USP on labor and delivery.

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
Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials. However, the use of dextrose and sodium chloride 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.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible dehydration.

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 the responses between 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. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

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

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

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment. As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

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 AVIVA 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>6E1033</td>
<td>500</td>
<td>0338-6315-03</td>
<td>2.5% Dextrose and 0.45% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1034</td>
<td>1000</td>
<td>0338-6315-04</td>
<td>2.5% Dextrose and 0.45% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1082</td>
<td>250</td>
<td>0338-6309-02</td>
<td>5% Dextrose and 0.2% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1083</td>
<td>500</td>
<td>0338-6309-03</td>
<td>5% Dextrose and 0.2% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1084</td>
<td>1000</td>
<td>0338-6309-04</td>
<td>5% Dextrose and 0.2% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1072</td>
<td>250</td>
<td>0338-6308-02</td>
<td>5% Dextrose and 0.6% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1073</td>
<td>500</td>
<td>0338-6308-03</td>
<td>5% Dextrose and 0.6% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1074</td>
<td>1000</td>
<td>0338-6308-04</td>
<td>5% Dextrose and 0.6% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1062</td>
<td>250</td>
<td>0338-6305-02</td>
<td>10% Dextrose and 0.5% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1063</td>
<td>500</td>
<td>0338-6305-03</td>
<td>10% Dextrose and 0.5% Sodium Chloride Injection, USP</td>
</tr>
<tr>
<td>6E1064</td>
<td>1000</td>
<td>0338-6305-04</td>
<td>10% Dextrose and 0.5% 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 AVIVA plastic container
To Open
Tear overwrap down side at slit and remove solution container. Moisture and 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
Caution: Do not use plastic containers in series connections.

Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication
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 Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Printed in USA

For Bar Code Position Only

PROOFREADING INSPECTION / RELEASED ARTWORK
Proofreading Approval
Print Name Signature Date

Proofreading Approval
Print Name Signature Date