SODIUM CHLORIDE Injection, USP
ADD-Vantage™ Diluent
Flexible Plastic Container
Rx only

ASSAULTION
Sodium Chloride Injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of sodium chloride in water for injection intended for intravenous administration after admixture with an ADD-Vantage (ADDAP) (see Aseptic Technique). WARNING: DO NOT USE WITH CHEMOTHERAPY AGENTS.

Concentrations

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Case of 24</th>
<th>Case of 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9%</td>
<td>100 mL</td>
<td>250 mL</td>
</tr>
<tr>
<td>0.45%</td>
<td>100 mL</td>
<td>250 mL</td>
</tr>
</tbody>
</table>

Caution must be exercised in the administration of parenteral solutions. The site of injection, extravasation and hypervolemia.

ADVERSE REACTIONS

None known.

WARNING

Sodium-containing sodium solutions should be used with great care. If, at all, in patients with heart failure, ascites, pleural or pericardial effusions, or edema, then sodium solution with sodium restriction.

Concomitant use of diuretic-free sodium solutions may result in significant hypernatremia. In patients with concomitant renal failure, administration of solutions containing sodium may be at risk of sodium toxicity. The inappropriate administration of these solutions can cause fluid and/or solute overloading resulting in diuresis of severe electrolyte concentrations, pericardial, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations and administration of parenteral solutions. The site of injection may be critical for patients with pericardial and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

CONTRAINDICATIONS

None known.

ADVERSE EFFECTS

Water retention may occur because of the sodium or the electrolyte concentrations that may be associated with edema and/or hypernatremia. Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrochemicals in the body compartments and sodium (Na+) plays a major role in maintaining physiological equilibrium.

INSTRUCTIONS FOR USE WITH ADD-VANTAGE VIAL

These instructions for use should be made available to the individuals who perform the reconstitution steps.

To Open:

1. Position the 3-way stopcock arm and remove solution container. 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.

2. If using a luer lock syringe, insert the inner cap into the vial through the walls of the container. (SEE FIGURE 4.)

3. Pull the inner cap from the drug vial. (SEE FIGURE 5.) Verify that the rubber stopper has been pulled out, leaving the drug vial in dilute form. (SEE FIGURE 6.)

4. Aliquot containers thoroughly and use within the specified time.

5. Look through the bottom of the vial to verify that the stopper has been removed and complete mixing has occurred. (SEE FIGURE 7.)

6. If the rubber stopper is not removed from the vial and medication is not released on the first attempt, the inner cap may be manipulated back into the rubber stopper without removing the drug vial from the dilution container. Repeat steps 2 through 5.

PRECAUTIONS

General

Use do not use sodium solutions in containers with serum. Such use could result in an adverse outcome due to material leaching from the primary container before administration of the fluid from the secondary container is completed.

Sodium Chloride Injection, USP contains minute amounts of sodium hydroxide, sodium carbonate, and sodium bicarbonate. These are not recommended for use with parenteral solutions. Use only with sodium chloride injection, USP.

Water for Injection, USP is chemically designated H2O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water for Injection, USP contains 180 mOsmol/L (calc.), which is isotonic.

Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

The pH of the fluid is 5.6 (4.5 to 7.0).

The fluid is isotonic with blood (285 mOsmol/L). It has a specific gravity of 1.006 to 1.008. At 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures may cause some losses in concentration; however, these losses usually are not clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and electrolytes. Water can be removed from the container into the patient's body but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out other electrolytes, water, and other chemicals which may affect the solution significantly.

Concerning Electrolyte: Solutions with Sodium Chloride Injection, USP, have not been reported to cause cardiac arrhythmias in patients who have had cardiac surgery. These solutions are compatible with aminoglycosides, beta-lactam agents, and other therapeutic interventions. Solutions with Sodium Chloride Injection, USP used for parenteral administration of blood components and other blood products usually are suitable for the dilution of blood components. Solutions with Sodium Chloride Injection, USP used for parenteral administration of blood components and other blood products generally are suitable for the maintenance of normal serum chloride concentrations. None known.

PREPARATION FOR ADMINISTRATION (see Aseptic Technique)

1. Confirm the activation and admixture of vial contents. (Use Aseptic Technique)

2. Insert vial into the diluent container.

3. Squeeze and release drip chamber to establish proper fluid level in chamber. (SEE FIGURE 3.)

4. Tie three tie strings, then pull back to remove the cover. (SEE FIGURE 1.)

5. Look through the bottom of the vial to verify that the stopper has been removed and complete mixing has occurred. (SEE FIGURE 2.)

6. Once the breakaway cap has been removed, do not access vial with any device except the supplied syringe. (SEE FIGURE 4.)

7. Squeeze and remove the cap. (SEE FIGURE 5.)

8. Once vial is seated, do not attempt to remove. (SEE FIGURE 6.)

9. To Reconstitute the Drug

10. Regulate rate of administration with flow control clamp.

11. Remove access device from vial and apply the appropriate dressing.

12. Place the stopcock on the secondary container.

13. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated. (NOTE: See full directions on administration set cart.)

14. Once vial is seated, do not attempt to remove. (SEE FIGURE 4.)

15. Insert the stopcock on the secondary container. (SEE FIGURE 5.)

16. If the drug vial has been opened, the stopcock should be reconfigured to the proper fluid level in the chamber. (SEE FIGURE 3.)

17. Squeeze and release drip chamber to establish proper fluid level in chamber. (SEE FIGURE 3.)

18. Open these control clamp and close air on set. Close clamp.

19. Attach set to venous device. (If device is notottle, prime and make sure clamp is closed.

20. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Sodium Chloride Injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of sodium chloride in water for injection intended for intravenous administration after admixture with an ADD-Vantage (ADDAP) (see Aseptic Technique). WARNING: DO NOT USE WITH CHEMOTHERAPY AGENTS.

Concentrations

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Case of 24</th>
<th>Case of 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9%</td>
<td>100 mL</td>
<td>250 mL</td>
</tr>
<tr>
<td>0.45%</td>
<td>100 mL</td>
<td>250 mL</td>
</tr>
</tbody>
</table>

Caution must be exercised in the administration of parenteral solutions. The site of injection, extravasation and hypervolemia.

ADVERSE REACTIONS

None known.

ADVERSE EFFECTS

Water retention may occur because of the sodium or the electrolyte concentrations that may be associated with edema and/or hypernatremia. Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrochemicals in the body compartments and sodium (Na+) plays a major role in maintaining physiological equilibrium.

INSTRUCTIONS FOR USE WITH ADD-VANTAGE VIAL

These instructions for use should be made available to the individuals who perform the reconstitution steps.

To Open:

1. Position the 3-way stopcock arm and remove solution container. 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.

2. If using a luer lock syringe, insert the inner cap into the vial through the walls of the container. (SEE FIGURE 4.)

3. Pull the inner cap from the drug vial. (SEE FIGURE 5.) Verify that the rubber stopper has been pulled out, leaving the drug vial in dilute form. (SEE FIGURE 6.)

4. Aliquot containers thoroughly and use within the specified time.

5. Look through the bottom of the vial to verify that the stopper has been removed and complete mixing has occurred. (SEE FIGURE 7.)

6. If the rubber stopper is not removed from the vial and medication is not released on the first attempt, the inner cap may be manipulated back into the rubber stopper without removing the drug vial from the dilution container. Repeat steps 2 through 5.

PRECAUTIONS

General

Use do not use sodium solutions in containers with serum. Such use could result in an adverse outcome due to material leaching from the primary container before administration of the fluid from the secondary container is completed.

Sodium Chloride Injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of sodium chloride in water for injection intended for intravenous administration after admixture with an ADD-Vantage (ADDAP) (see Aseptic Technique). WARNING: DO NOT USE WITH CHEMOTHERAPY AGENTS.

Concentrations

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Case of 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9%</td>
<td>100 mL</td>
</tr>
<tr>
<td>0.45%</td>
<td>100 mL</td>
</tr>
</tbody>
</table>

Caution must be exercised in the administration of parenteral solutions. The site of injection, extravasation and hypervolemia.

ADVERSE REACTIONS

None known.

ADVERSE EFFECTS

Water retention may occur because of the sodium or the electrolyte concentrations that may be associated with edema and/or hypernatremia. Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrochemicals in the body compartments and sodium (Na+) plays a major role in maintaining physiological equilibrium.

INSTRUCTIONS FOR USE WITH ADD-VANTAGE VIAL

These instructions for use should be made available to the individuals who perform the reconstitution steps.