

## **0.9% Sodium Chloride Injection, USP** **in MINI-BAG Plus Container** **VIAFLEX Plastic Container**

### **DESCRIPTION**

0.9% Sodium Chloride Injection, USP in the MINI-BAG Plus Container is a sterile, nonpyrogenic solution for intravenous administration after admixture with a single dose powdered drug. It contains no antimicrobial agents. The nominal pH is 5.0 (4.5 to 7.0). Each 100 mL contains 900 mg of Sodium Chloride, USP (NaCl). The osmolarity is 308 mOsmol/L (calculated). It contains 154 mEq/L sodium and 154 mEq/L chloride.

The MINI-BAG Plus Container is a standard diluent container with an integral drug vial adaptor. It allows for drug admixture after connection to a **single dose** powdered drug vial having a **20 mm closure**. A breakaway seal in the tube between the vial adaptor and the container is broken to allow transfer of the diluent into the vial and reconstitution of the drug. The reconstituted drug is then transferred from the vial into the container diluent and mixed to result in an admixture for delivery to the patient.

The VIAFLEX Plastic Container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. 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 chemical components from the plastic in very small amounts. However, biological testing was supportive of the safety of the plastic container materials.

### **CLINICAL PHARMACOLOGY**

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

### **INDICATIONS AND USAGE**

0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes and may also be used as diluent for reconstitution of a powdered drug product packaged in a vial with a 20 mm closure.

## CONTRAINDICATIONS

None known.

## WARNINGS

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection, USP.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Depending on the volume and rate of infusion, the intravenous administration of Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration/hypervolemia, congested states, pulmonary edema, or acid-base imbalance. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Administer 0.9% Sodium Chloride Injection, USP with particular caution to patients with or at risk for hyponatremia, hyperchloremia, or metabolic acidosis.

Administer 0.9% Sodium Chloride Injection, USP with particular caution, to patients with or at risk for hypervolemia or with conditions that may cause sodium retention, fluid overload and edema; such as patients with primary hyperaldosteronism, or secondary hyperaldosteronism [ e.g., associated with hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis) or pre-eclampsia]. Certain medications may increase risk of sodium and fluid retention, see **Drug Interactions**.

Administer 0.9% Sodium Chloride Injection, USP with particular caution to patients with severe renal impairment. In such patients, administration of 0.9% Sodium Chloride Injection, USP may result in sodium retention.

For use only with a single dose powdered drug vial with a 20 mm closure.

Do not administer unless drug is completely dissolved and drug vial is empty. Do not remove drug vial at any time prior to or during administration.

## **PRECAUTIONS**

### **General**

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. 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.

Rapid correction of hypernatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in intravenous fluid therapy.

### **Drug Interactions**

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be decreased in the presence of **hyponatremia**.

### **Pregnancy**

#### *Pregnancy Category C*

There are no adequate and well controlled studies with Sodium Chloride Injection, USP, in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman. Sodium Chloride Injection, USP should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### **Nursing Mothers**

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

### **Pediatric Use**

The use of Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. (See **DOSAGE AND ADMINISTRATION**.)

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

### **Geriatric Use**

Clinical studies of 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.

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**

### **Post-Marketing Adverse Reactions**

The following adverse reactions have been identified during postapproval use of 0.9% Sodium Chloride Injection, USP. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported in the post-marketing experience during use of 0.9% Sodium Chloride Injection, USP and include the following:

hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus.

Also reported are infusion site reactions, such as infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria.

The following adverse reactions have not been reported with 0.9% Sodium Chloride Injection, USP but may occur: hypernatremia, hyperchloremic metabolic acidosis, and hyponatremia, which may be symptomatic.

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.

## **OVERDOSAGE**

Excessive administration of 0.9% Sodium Chloride Injection, USP may lead to hypernatremia. Hypernatremia can lead to CNS manifestations including seizures, coma, cerebral edema and death.

Excessive administration of 0.9% sodium chloride may lead to sodium overload (which can lead to central and/or peripheral edema).

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.

## **DOSAGE AND ADMINISTRATION**

All injections in MINI-BAG Plus containers are intended for intravenous administration using sterile and nonpyrogenic equipment.

As directed by a physician. Dosage, rate, and duration of administration are to be individualized and depend upon the indication for use, the patient's age, weight, clinical condition, concomitant treatment, and on the patient's clinical and laboratory response to treatment.

When other electrolytes or medicines are added to this solution, the dosage and the infusion rate will also be dictated by the dose regimen of the additions.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

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

Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier.

Additives may be incompatible with 0.9% Sodium Chloride Injection, USP. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Sodium Chloride Injection, USP is appropriate. After addition, check for unexpected color changes and/or the appearance of precipitates, insoluble complexes or crystals.

The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible must not be used. When introducing additives to Sodium Chloride Injection, USP, aseptic technique must be used.

Mix the solution thoroughly when additives have been introduced.

Do not store solutions containing additives.

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion. Do not reconnect any partially used containers. Discard any unused portion.

### **HOW SUPPLIED**

0.9% Sodium Chloride Injection, USP in MINI-BAG Plus Container is available as follows:

<b>Code</b>	<b>Size (mL)</b>	<b>NDC</b>
2B0042	50	0338-0553-11
2B0043	100	0338-0553-18

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F).

## DIRECTIONS FOR USE

For Information on Risk of Air Embolism – see **PRECAUTIONS**.

### 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.

Prior to use, check that the vial adaptor cover is intact. Check the solution container for minute leaks by squeezing inner bag firmly. If leaks are found or if the vial adaptor cover is not intact, discard product as sterility may be impaired.

### To Assemble and Reconstitute

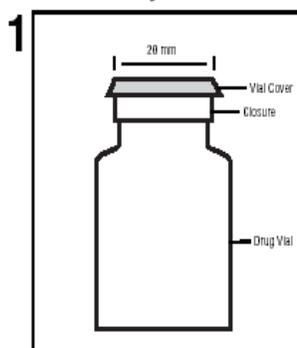
See diagram for detailed instructions.

## MINI-BAG Plus Container Directions

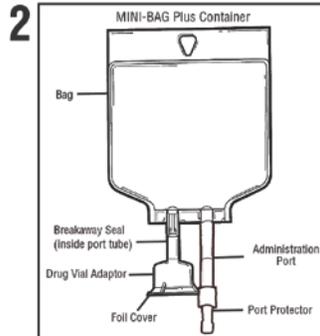
Only For Single Dose Powdered Drug Vials with 20 mm Closures

Use Aseptic Technique

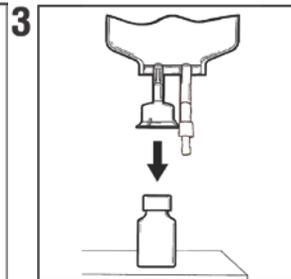
### Assembly



- Remove vial cover.
- Disinfect stopper.

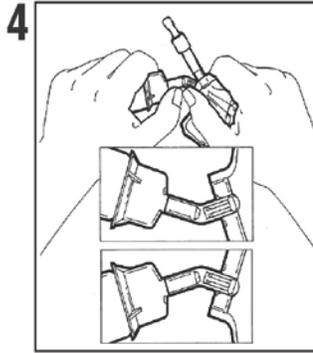


- Peel off foil cover.
- Inspect adaptor for moisture. Discard if found.

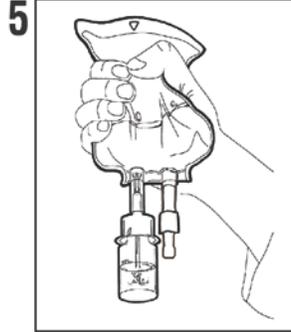


- Place vial upright.
- Hold firmly.
- Push adaptor down until vial snaps in place.
- DO NOT TWIST.
- Pull vial to ensure fully seated.

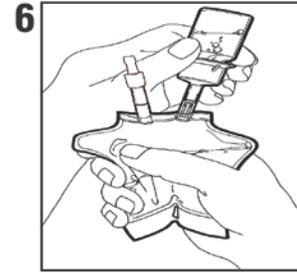
### Reconstitution



- Squeeze bag and check vial.
- Use only if vial fully seated and dry.
- Bend up then down to break seal.



- Hold bag with vial down.
- Squeeze solution into vial until half full.
- Shake to suspend drug in solution.



- Hold bag with vial upside down.
- Squeeze bag to force air into vial.
- Release to drain suspended drug from vial.
- Repeat steps 5 and 6 until vial is empty of drug and solution is thoroughly mixed. **Ensure drug is completely dissolved. Do Not Remove Drug Vial.**

7 Remove port protector. Attach administration set per its directions.

8 Hang container on I.V. pole and prime set per directions. Ensure that vial is empty of drug and solution. Repeat step 6 if drug and solution remain in vial.

**Warning:** Do not use in series connections.

9 Administer medication per directions. Use within specified time for drug stability.

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