Baxter

# Mini-**Bag Plus**

SINGLE PACK

## **Mini-Bag Plus** container system

Directions for assembly and reconstitution of the 0.9% Sodium Chloride Injection, USP in **Mini-Bag Plus** container and 5% Dextrose Injection, USP in **Mini-Bag Plus** container. Only for single-dose, powdered or liquid (up to 10 mL) drug vials with a 20 mm closure.

**Use Aseptic Technique.**

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

Please refer to the respective drug manufacturer labeling, not all drugs are compatible with the **Mini-Bag Plus** container.

## ASSEMBLY*//

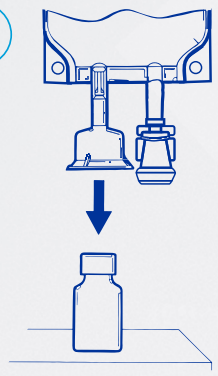
**1**


- Remove vial cover
- Disinfect stopper

**2**


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

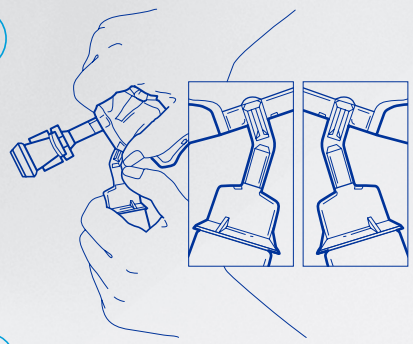
**3**



- Place vial upright
- Hold firmly
- Push adaptor down until vial snaps in place
- **DO NOT TWIST**

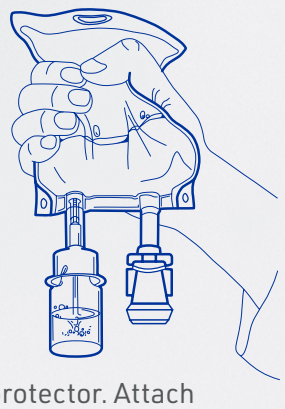
## RECONSTITUTION*//

**4**



- Squeeze bag and check vial
- Use only if vial is fully seated and dry
- With vial in an upright position break the seal by fully bending back and forth until a clear gap is observed in the breakaway seal

**5**

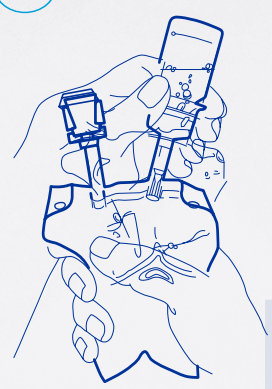


**For liquid drug vials proceed directly to step 6.**

**For powdered drug vials:**

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

**6**



- 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 institutional practices

**10** Use within specified time for drug stability

**11** Discard unused portion

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.

For 5% Dextrose Injection, USP only: Prior to adding the medication, verify that it is soluble and/or stable in Dextrose Injection and that the pH range is appropriate.

### INDICATIONS FOR 0.9% SODIUM CHLORIDE INJECTION, USP

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 or liquid (up to 10 mL) drug product packaged in a vial with a 20 mm closure.

**Select Risk Information**

- Hypersensitivity and 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.

### INDICATIONS FOR 5% DEXTROSE INJECTION, USP

5% Dextrose Injection, USP is indicated as source of water and calories and may also be used as diluent for reconstitution of a powdered or liquid (up to 10 mL) drug product packaged in a vial with a 20 mm closure.

**Select Risk Information**

- The use of Dextrose Injection is contraindicated in patients with clinically significant hyperglycemia or known hypersensitivity to dextrose.

**Please see the additional Important Risk Information to follow.**

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# Indications and Important Risk Information

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

**Indications:** 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 or liquid (up to 10 mL) drug product packaged in a vial with a 20 mm closure.

### Important Risk Information

- Hypersensitivity and 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.
- Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Sodium Chloride Injection, USP can cause fluid disturbance such as overhydration/hypervolemia and congested states, including pulmonary congestion and edema. Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for fluid and/or solute overloading.
- 0.9% Sodium Chloride Injection, USP may cause hyponatremia. The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release treated with high volume of Sodium Chloride Injection, USP. The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, in those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). Patients at increased risk for developing complications of hyponatremia such as hyponatremic encephalopathy (characterized by headache, nausea, seizures, lethargy, and vomiting), include pediatric patients, women (in particular pre-menopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.
- Hypernatremia may occur with Sodium Chloride Injection, USP. Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease, renal disease; and pre-eclampsia. Certain medications such as corticosteroids or corticotropin, may also increase the risk of sodium and fluid retention. Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.
- Administration of 0.9% Sodium Chloride Injection, USP in patients with or at risk of severe renal impairment, may result in hypernatremia and/or fluid overload. Avoid Sodium Chloride Injection, USP in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention, fluid overload, or edema.
- The following adverse reactions have been reported in the post-marketing experience: hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, pruritus, infusion site reactions, such as infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria, hypernatremia, hyperchloremic metabolic acidosis, and hyponatremia, which may be symptomatic, hyponatremic encephalopathy.
- Renal sodium and lithium clearance may be decreased or increased during administration of sodium chloride. Monitor serum lithium concentrations during concomitant use.

**Please see full Prescribing Information.**

### 5% Dextrose Injection, USP in MINI-BAG Plus Container

**Indications:** 5% Dextrose Injection, USP is indicated as source of water and calories and may also be used as diluent for reconstitution of a powdered or liquid (up to 10 mL) drug product packaged in a vial with a 20 mm closure.

### Important Risk Information

- The use of Dextrose Injection is contraindicated in patients with clinically significant hyperglycemia or known hypersensitivity to dextrose.
- The use of dextrose infusions in patients with impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death. Hyperglycemia is associated with an increase in serum osmolality, resulting in osmotic diuresis, dehydration and electrolyte losses. Patients with underlying CNS disease and renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state. Monitor blood glucose levels and treat hyperglycemia to maintain levels within normal limits while administering Dextrose Injection.
- Hypersensitivity and infusion reactions including anaphylaxis, have been reported with Dextrose Injection. Stop infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop.
- Consider central vein when administering more than 5% dextrose or with an osmolarity of ≥900 mOsm/L or when there is peripheral vein irritation, phlebitis, and/or associated pain. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis.
- Intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatremia. Monitor serum sodium to minimize the risk of hyponatremia. The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). Avoid Dextrose Injection in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.
- Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions. Depending on the volume and rate of infusion, the intravenous administration of dextrose solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations (including hypoosmotic hyponatremia, overhydration, congested states or pulmonary edema. Avoid Dextrose Injection in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor daily fluid balance, electrolyte concentrations, and acid-base balance, as needed and especially during prolonged use.
- Refeeding severely undernourished patients may result in refeeding syndrome. Thiamine deficiency and fluid retention may also develop. Monitor severely undernourished patients and slowly increase nutrient intakes.
- The most common adverse reactions are hyperglycemia, hypersensitivity reactions, hyponatremia, infection both systemic and at the injection site, vein thrombosis or phlebitis, and electrolyte imbalance.
- Monitor blood glucose concentrations, fluid balance, serum electrolyte concentrations and acid-base balance when using Dextrose Injection in patients treated with other substances that affect glycemic control, vasopressin or fluid and/or electrolyte balance.
- Neonates are at increased risk of developing hypo- or hyperglycemia and need close monitoring during treatment with intravenous glucose infusions to ensure adequate glycemic control to avoid potential long-term adverse effects.

**Please see full Prescribing Information.**

**References: 1.** Baxter. Internal Data on File. **2.** Baxter. Internal Data on File (Market Research).


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