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Rx

0.9%

Sodium Chloride Injection, USP
in VIAFLEX Plastic Container

Description
0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH and ionic concentration are shown in Table 1,
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
0.9% 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.
0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

Contraindications
None known.

Warnings
0.9% 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.

<u>Hypersensitivity reactions</u>
- Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus, have been reported with Sodium Chloride Injection, USP.
- Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

<u>Risk of Fluid and/or Solute Overload and Electrolyte Disturbances</u>
Depending on the volume and rate of infusion, intravenous administration of Sodium Chloride Injection, USP can cause:
- fluid and/or solute overload resulting in overhydration/hypervolemia and, for example, congested states, including central and peripheral edema.
- clinically relevant electrolyte disturbances and acid-base imbalance.

<u>Use in patients at risk for sodium retention, fluid overload and edema</u>
Sodium Chloride Injection, USP should be used with particular caution, if at all, in patients

with or at risk for:

- Hypernatremia
- Hyperchloremia
- Metabolic acidosis
- Hypervolemia
- Medications that may increase the risk of sodium and fluid retention, such as corticosteroids.

In general, the risk of dilutional states is inversely proportional to the electrolyte concentrations of 0.9% Sodium Chloride Injection, USP and additions. The risk of solute overload causing congested states is directly proportional to the electrolyte concentrations of 0.9% Sodium Chloride Injection, USP and additions.

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.

Hyponatremia

Sodium Chloride Injection, USP may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of Sodium Chloride Injection, USP.

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).

Patients at increased risk for developing complications of hyponatremia such as hyponatremic encephalopathy, include pediatric patients, women (in particular pre-menopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

Hypernatremia

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 (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia.

Certain medications, such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention.

Avoid Sodium Chloride Injection, USP in patients with, or at risk for, hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hypernatremia is potentially dangerous with risk of serious neurologic complications. Excessively rapid correction of hypernatremia is also associated with a risk for serious neurologic complications such as osmotic demyelination syndrome (ODS) with risk of seizures and cerebral edema.

Use in Patients with Severe Renal Impairment
Sodium Chloride Injection, USP should be administered with particular caution, if at all, to patients with severe renal impairment. In such patients administration of Sodium Chloride Injection, USP may result in sodium retention.

Precautions
Risk of Air Embolism

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

Interactions with Other Medicinal Products and Other Forms of Interaction
Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Sodium Chloride Injection, USP. Administration of Sodium Chloride Injection, USP, may result in decreased lithium levels.

Administration of Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia. Avoid use of Sodium Chloride Injection, USP in patients receiving products, such as diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

Administration of Sodium Chloride Injection, USP to patients treated concomitantly with drugs associated with sodium and fluid retention may increase the risk of hypernatremia and volume overload. Avoid use of Sodium Chloride Injection, USP in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance.

Pregnancy, Lactation, and Fertility
There are no adequate data from the use of Sodium Chloride Injection, USP in pregnant or lactating women. Physicians should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride Injection, USP.

Use in Pediatric Patients
Plasma electrolyte concentrations should be closely monitored in the pediatric population because of their impaired ability to regulate fluids and electrolytes.

In very low birth weight infants, excessive or rapid administration of Sodium Chloride Injection, USP may result in increased serum osmolality and risk of intracerebral hemorrhage. Children (including neonates and older children) are at increased risk of developing hyponatremic encephalopathy.

Use in Geriatric Patients

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy. Therefore, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range. Consider monitoring renal function in elderly patients.

Adverse Reactions

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

Post-marketing Adverse Reactions

- IMMUNE SYSTEM DISORDERS: Hypersensitivity/infusion reactions, including Hypotension, Pyrexia, Tremor, Chills, Urticaria, Rash, Pruritus
- GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions, such as Infusion site erythema, Injection site streaking, Burning sensation, Infusion site urticaria.
- NERVOUS SYSTEM DISORDERS: Hyponatremic encephalopathy

Other Adverse Reactions / Class Reactions

The following adverse reactions have not been reported with this product but may occur:

- Hypernatremia
- Hyperchloremic metabolic acidosis
- 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 fluid for examination if deemed necessary

Overdose

An excessive volume of [Sodium Chloride 0.9%] may lead to hypernatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema and death) and 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

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 and concomitant treatment, and on the patient 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. Do not administer unless solution is clear and seal is intact

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

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. 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. The instructions for use of the medication to be added and other relevant literature must be consulted. After addition, check for a possible color change and/or the appearance of precipitates, insoluble complexes or crystals.

Mix thoroughly when additives have been introduced. Do not store solutions containing additives. For single use only. Discard any unused portion.

Availability
Table 1 shows the available sizes of each injection in VIAFLEX plastic containers. Not all pack sizes may be marketed.

Directions for use of VIAFLEX plastic container
Warning: 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. See Precautions.

To Open
Tear overwrap down side at slit 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. 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 “to add medication” directions below.

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

To Add Medication
Warning: Additives known or determined to be incompatible should not be used. See Dosage and Administration.
To add medication before solution administration
1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

Storage
Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at temperature not exceeding 30°C; brief exposure up to 40°C does not adversely affect the product.

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

Caution:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Keep out of reach of children.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

Table 1	Sodium Chloride, USP (NaCl) (g/L)	Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)		How Supplied	
				Sodium	Chloride	Size (mL)	Code
0.9% Sodium Chloride Injection, USP	9.0	308	5.0 (4.5 to 7.0)	154	154	50 100 250 500 1000 2000	F8B1306 F8B1307 F8B1322 F8B1323 F8B1324 F8B0057

Manufactured and Distributed by:
Baxter Healthcare Philippines, Inc.
Silangan Industrial Estate, Brgy. Canlubang
Calamba City, Laguna, Philippines

Date of Authorization Renewal: 06 August 2019
Date of Last Revision: March 2022
Registration Number: DR-XY14635-L
Pack Size: 100 mL, 500 mL, 1000 mL

Date of Authorization Renewal: 14 May 2019
Date of Last Revision: March 2022
Registration Number: DR-XY43412 (For Export Only)
Pack Size: 50 mL

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