

PRESCRIBING INFORMATION

3% Sodium Chloride Injection, USP
5% Sodium Chloride Injection, USP

IV Fluid and Electrolyte Replenisher

Baxter Corporation
Mississauga, Ontario L5N 0C2
Canada

Date of Revision:
November 3, 2016

Submission Control No: 168812
Baxter and Viaflex are Trademarks of Baxter International Inc.

Prescribing Information

3% and 5% Sodium Chloride Injections, USP in Vialflex Plastic Container

Summary Product Information

Made of sodium chloride (NaCl) and water, 3% and 5% Sodium Chloride Injections, USP are sterile, nonpyrogenic, hypertonic solutions for fluid and electrolyte replenishment in single dose containers for intravenous administration.

Table 1. Composition, osmolarity and pH of 3% and 5% Sodium Chloride Injections, USP

Product	Composition & concentration	Ionic concentration (mmol/L)		Total osmolarity (mOsmol/L)	Approx pH	Volume (ml)
	Sodium Chloride (g/L)	Na ⁺	Cl ⁻			
3% Sodium Chloride Injection, USP	30	513	513	1027	5.0	250
5% Sodium Chloride Injection, USP	50	856	856	1711	5.0	250

Composition, osmolarity, and approximate pH of these products are shown in Table 1.

The **Vialflex** 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.

Indications and Clinical Use

3% and 5% Sodium Chloride Injections, USP are indicated as a source of water and electrolytes.

They are capable of inducing diuresis depending on the clinical condition of the patient. See Table 1 for ionic concentration.

Contraindications

3% and 5% Sodium Chloride Injections, USP are contraindicated in patients who are hypersensitive to the drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Prescribing Information.

Warnings and Precautions

General

3% and 5% Sodium Chloride Injections, USP are strongly hypertonic and may cause vein damage.

3% and 5% Sodium Chloride Injections, 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.

In patients with diminished renal function, administration of 3% and 5% Sodium Chloride Injections, USP may result in sodium retention.

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). [See **Dosage and Administration**]

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.

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus may occur.

Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Risk of Fluid and/or Solute Overload and Electrolyte Disturbances

Depending on the volume and rate of infusion, intravenous administration of 3% and 5% Sodium Chloride Injections, 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

In general, the risk of fluid/solute overload causing congested states and/or electrolyte disturbances is directly proportional to the volume of the products intravenously administered.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance.

Use in patients at risk for sodium retention, fluid overload and edema

3% and 5% Sodium Chloride Injections, USP should be used with particular caution, if at all, in patients with or at risk for:

- Hyponatremia
- Hyperchloremia
- Hypervolemia
- Conditions that may cause sodium retention, fluid overload and edema (central and peripheral), such as patients with
 - o primary hyperaldosteronism,
 - o secondary hyperaldosteronism associated with, for example,
 - hypertension
 - congestive heart failure,

- liver disease (including cirrhosis),
 - renal disease (including renal artery stenosis, nephrosclerosis) or
 - pre-eclampsia.
- Medications that may increase the risk of sodium and fluid retention, such as corticosteroids

Use in Patients with Severe Renal Impairment

3% and 5% Sodium Chloride Injections, USP should be administered with particular caution, if at all, to patients with severe renal impairment. In such patients administration of 3% and 5% Sodium Chloride Injections, USP may result in sodium retention.

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.

Osmolarity

3% and 5% Sodium Chloride Injections, USP are hypertonic with an osmolarity of:

3% Sodium Chloride Injection, USP: 1027 mOsm/L

5% Sodium Chloride Injection, USP: 1711 mOsm/L.

3% and 5% Sodium Chloride Injections, USP may cause vein damage. Thus it should be administered through a large central vein, for rapid dilution of the hypertonic solution.

Special Populations

Pediatrics

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

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

Geriatrics

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, one should consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

Pregnant or Nursing Women

There are no adequate data from the use of 3% and 5% Sodium Chloride Injections, USP in pregnant or lactating women. Healthcare providers should carefully consider the potential risks and benefits for each specific patient before administering 3% and 5% Sodium Chloride Injections, USP.

3% and 5% Sodium Chloride Injections, USP should be given to a pregnant woman only if clearly needed.

Adverse Reactions

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

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.

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

- Hyperchloremic metabolic acidosis
- Infusion site reactions, such as thrombosis, phlebitis, irritation, infusion site erythema, injection site streaking, burning sensation, infusion site urticaria.

Drug Interactions

Caution is advised in patients treated with lithium. Renal lithium clearance may be increased during administration of 3% and 5% Sodium Chloride Injections, USP, resulting in decreased lithium levels.

Caution is advised when administering 3% and 5% Sodium Chloride Injections, USP to patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids or corticotropin [See also **Warnings and Precautions - Use in patients at risk for sodium retention, fluid overload and edema.**]

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's clinical and laboratory response to treatment.

Rapid correction of hyponatremia and 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.

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.

3% and 5% Sodium Chloride Injections, USP are intended for intravenous administration using sterile equipment.

It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

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.

Administration with Blood Products

Do not mix or administer 3% and 5% Sodium Chloride Injections, USP through the same administration set with whole blood or cellular blood components.

Overdosage

An excessive volume of 3% and 5% Sodium Chloride Injections, USP may lead to

- hyponatremia (which can lead to CNS manifestations, including seizures, coma, cerebral edema and death)
- sodium overload (which can lead to central and/or peripheral edema).
- hypokalemia which may lead to cardiac arrhythmia, cardiac arrest, acute confusion state or death

Should overdose occur, prompt and careful clinical and laboratory assessment is essential. Effective therapeutic intervention based on the condition of the patient should be planned and executed as soon as possible.

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat.

Store at 15°C to 25°C.

Special Handling Instructions

For single use only.

Discard any unused portion.

Dosage Form, Composition and Packaging

How Supplied

See Summary Product Information, Table 1 which shows the ionic composition, osmolarity, approx. pH and volume of 3% and 5% Sodium Chloride Injections, USP.

Directions for use of Vialflex Plastic Containers

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.

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. Squeeze and inspect bag. Discard if leaks are found. If supplemental medication is desired, follow directions below before preparing for administration.

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 may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture 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.

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.

Baxter Corporation

Mississauga, ON L5N 0C2

Baxter, Viaflex and PL 146 are trademarks of Baxter International Inc.