**NACELLATE SOLUTION 0.9% - 250ML- sodium chloride injection, solution**
**IT3 Medical LLC**

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**Nacellate Solution 0.9% - 250mL**

## DESCRIPTION

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. The nominal pH is 5.0 (4.5 to 7.0). Composition, osmolarity, and ionic concentration are shown below:

**0.45% Sodium Chloride Injection, USP** contains 4.5 g/L Sodium Chloride, USP (NaCl) and is hypotonic with an osmolarity of 154 mOsmol/L (calc). It contains 77 mEq/L sodium and 77 mEq/L chloride.

**0.9% Sodium Chloride Injection, USP** contains 9 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 308 mOsmol/L (calc). It contains 154 mEq/L sodium and 154 mEq/L chloride.

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

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

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

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills,

urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection, USP and may occur with 0.45% 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 hypernatremia, hyperchloremia, or metabolic acidosis.

The infusion of solutions with 0.45% Sodium Chloride Injection, USP may result in hyponatremia. Close clinical monitoring may be warranted. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death. The risk for hyponatremia is increased, for example, in children, elderly, women, postoperatively, in persons with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as certain antiepileptic and psychotropic medications). The risk for developing hyponatremic encephalopathy is increased, for example, in pediatric patients (≤16 years of age), women (in particular pre-menopausal women), in patients with hypoxemia, and in patients with underlying central nervous system disease. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

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

## 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.

Do not mix or administer 0.45% Sodium Chloride Injection, USP through the same administration set with whole blood or cellular blood components.

Rapid correction of hypo- 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.

### 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. Administration of 0.45% Sodium Chloride Injection, USP may result in increased lithium levels.

Renal sodium and lithium clearance may be increased during administration of 0.9% Sodium Chloride Injection, USP. Administration of 0.9% Sodium Chloride Injection, USP, may result in decreased lithium levels.

### Pregnancy

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 to a 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.

The infusion of hypotonic fluids (0.45% Sodium Chloride Injection, USP) together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute

volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

### 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 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.

Hyponatremia has been reported for 0.45% Sodium Chloride Injection, USP (see Pediatric Use section).

The following adverse reactions have not been reported with 0.45% Sodium Chloride Injection, USP but may occur: hyperchloremic metabolic acidosis, hypersensitivity/infusion reactions (including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus), and infusion site reactions (such as infusion site erythema, injection site streaking, burning sensation, infusion site urticaria).

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 0.45% Sodium Chloride Injection, USP may lead to hypo- and hypernatremia, while excessive administration of 0.9% Sodium Chloride Injection, USP may lead to hypernatremia. Both hypo- and hypernatremia can lead to CNS manifestations, including seizures, coma, cerebral edema and death.

Excessive administration of Sodium Chloride Injection, USP 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 VIAFLEX plastic 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 the solution is clear and seal is intact.

Additives may be incompatible with 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

The available sizes of each injection in VIAFLEX plastic containers are shown below:

| Code | Size (mL) | NDC | Product Name |
|---|---|---|---|
| 2B1322 | 250 | 70529-022-01 | 0.9% Sodium Chloride Injection, USP |

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); brief exposure up to 40°C/104°F does not adversely affect the product.

## DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

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. 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 directions below.

### Preparation for Administration

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

### To Add Medication

Additives may be incompatible

### 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.

### 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.

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Assembled and Distributed by IT3 Medical, LLC 190 E Stacy Road; STE 306-298, Allen, TX 75002-8734
For questions or comments: info@IT3-Medical.com, www.IT3-Medical.com

**Packaging**

NDC 70529-022-01

Rx ONLY

IT3

# Nacellate Solution 0.9% - 250mL Injection System

Contents:

1 - 250mL Sodium Chloride Injection 0.9%

Single use only

Caution, consult accompanying documents

Consult instructions for use

25°C 77°F

20°C 68°F

Temperature limitations

Storage: Store in a cool dry place at 25°C (77°F). Excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

Lot/Expiration

Lot : 111617
Exp : 8-1-18

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**NACELLATE SOLUTION 0.9% - 250ML**

sodium chloride injection, solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70529-022 |
| **Route of Administration** | INTRAVENOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) | SODIUM CHLORIDE | 9 g in 1000 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:70529-022-01 | 1 in 1 PACKAGE | 03/01/2017 | |
| **1** | | 250 mL in 1 BAG; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA016677 | 03/01/2017 | |

## Labeler - IT3 Medical LLC (079971231)

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