Product Information for Sodium Chloride Injection 0.9% Rx Only

WARNING: Please carefully check before use. Do not use the drug solution if there is turbidity or foreign matter, bag body damage or leaks.
Disclaimer: This drug is not approved by FDA.

DRUG NAME: Sodium Chloride Injection, 0.9%
INGREDIENT: Active ingredient: Sodium Chloride Excipients: dilute hydrochloric acid/sodium hydroxide for pH adjustment, water for injection
CHEMICAL NAME: Sodium Chloride; Molecular Formula: NaCl; Molecular Weight: 58.44.
DESCRIPTION: A clear, colorless liquid. Sodium Chloride Injection is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It is sterile, nonpyrogenic, and contain no antimicrobial agents. It contains 9 g/L Sodium Chloride, (NaCl). It contains 154 mEq/L sodium and 154 mEq/L chloride.

CLINICAL PHARMACOLOGY: Sodium Chloride Injection provides electrolytes and is a source of water for hydration. Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids.

PHARMACOKINETICS: Sodium chloride enters the blood circulation directly after intravenous injection and is widely distributed in the body but is mainly present in the extracellular fluid. It is excreted in the urine by the kidneys and only a small fraction is excreted by sweat.

RECOMMENDED USAGE Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient

Can also be used for Water loss due to various causes, including hypotonic, isotonic and hyperosmolar water loss; hyperosmolar nonketotic diabetic coma can be corrected by isotonic or hypotonic sodium chloride; hypochlorine metabolic alkalosis; irrigation of eyes with topical normal saline, washing wounds; it is also used in obstetric water sacs to induce labor.

WARNINGS: Sodium Chloride Injections 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. The intravenous administration of Sodium Chloride Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections. In patients with diminished renal function, administration of Sodium Chloride Injection may result in sodium retention.

PRECAUTIONS: Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one

container before administration of the fluid from a 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. Before use, carefully check the product. Do not use if there is turbidity, foreign matter, damage to the bag, or leakage.

Pregnant and nursing mothers. It is also not known whether Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection should be given to a pregnant woman only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride Injection is administered to a nursing woman.
Animal reproduction studies have not been conducted with Sodium Chloride Injection. It is also not known whether Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity

Pediatric medication: The volume and speed of rehydration should be strictly controlled. Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

Drug interaction: When used as a drug solvent or diluent, attention should be paid to incompatibility between drugs.

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.

OVERDOSE: Can cause hypernatremia and hypokalemia and can cause bicarbonate loss. In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures.

DOSAGE AND ADMINISTRATION:

As directed by a physician. Adjust dosage depending on the age, weight and clinical condition of the patient as well as laboratory determinations. 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 injections in UNIFLEX© containers are intended for intravenous administration using sterile equipment. Additives may be incompatible. Those additives known to be incompatible should not be used.

Consult with pharmacist. 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.

HOW SUPPLIED: Sodium Chloride Injection is supplied in single-dose plastic containers as follows

Volume	Product Number	Packaging
250 mL	GYZZ H51021157	Uniflex PP container

STORAGE: Store at room temperature (10°C -30°C/50°F-86°F), in well-closed container to maintain sterility and stability. Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat.

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DISTRIBUTED BY: ApiJect Systems, Corp. Telephone: (855) 826-4885