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Sodium Chloride Injection 0.9%
Solution for Injection.

In Non PVC Bags

Description
Sodium Chloride Injection 0.9% solution for injection in Non PVC Bags is sterile, nonpyrogenic solution for fluid and electrolytes replenishment in single dose bags for intravenous administration. It contains no antimicrobial agents. The composition, osmolarity, and pH values are shown in Table 1.

Table 1
Composition, Osmolarity, and Approximate pH Values

	Sodium Chloride (g/L)	Osmolarity* (mOsm/L)	Approx. pH **Values
Sodium Chloride Injection 0.9% Solution for Injection	9.0	308	5.0

* Normal physiologic isotonicity range is approximately 280-310 mOsm/L.
Administration of substantially hypotonic solutions may cause hemolysis, and administration of substantially hypertonic solutions may cause vein damage.
**Approx. pH values are USP for applicable solutions, corporate specification for non-USP solutions.

Approximate ionic concentrations (mEq/L) and calories per liter are shown in Table 2.

Table 2
Approximate Ionic Concentrations (mEq/L) and Calories per liter

	Sodium	Chloride	Caloric content (Kcal/L)
Sodium Chloride Injection 0.9% Solution for Injection	154	154	0

Description of the Primary Bags:

Type and size: Non PVC plastic bag +overpouch; size: 1000 ml.
Material composition:

- Non PVC plastic film, based on polyethylene, polyamide, and polypropylene.
- Overpouch based on co-extruded blend: polypropylene/polyamide/polypropylene film.

Clinical Pharmacology

As a source of water and electrolytes and capable of inducing diuresis depending on the clinical condition of the patient.

For caloric value see Table 2.

Indications

A source of water and electrolytes.

Also indicated for use as priming solutions in hemodialysis procedures.

Contraindications

None known.

Warnings

General

Note: Dispensing without Doctor's prescription is prohibited.

The administration of Intravenous Injections can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations 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.

Excessive administration of potassium-free solutions may result in significant hypokalemia.

In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.

Administration by central venous catheter should be used only by those familiar with this technique and its complications.

For Solutions Containing Sodium Ions

Solutions containing sodium ions 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 Sodium Chloride Injections may result in sodium retention.

Use in Pregnancy

Animal reproduction studies have not been conducted. It is also not known whether these solutions can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Therefore, these solutions should be given to a pregnant woman only if clearly needed.

Use in Pediatrics

Use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Adverse Reactions

General

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.

Nausea, fever, and flushing of the skin have occurred.

If an adverse reaction does occur, the infusions should be discontinued, the patient evaluated, appropriate therapeutic countermeasures instituted, and the remainder of the fluid saved for examination if deemed necessary.

Precautions

General

Do not administer unless the solution is clear and the seal is intact.

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.

Caution should be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Caution should be exercised in the administration of these injections to the very young and to elderly patients.

Administer so that extravasation does not occur. If thrombosis occurs during administration, stop injection and correct.

Dosage and Administration

Note: Do not administer unless solution is clear and seal is intact.

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.

The dosage is usually dependent upon the age, weight and clinical condition of the patient, as well as laboratory determinations. All injections in plastic bags 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. A pharmacist should be consulted, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, aseptic technique should be used. Thorough mixing should be performed when additives have been introduced. *Solutions containing additives must not be stored.*

Directions for Use of Plastic Bags

Warning : Do not use plastic bags in series connections. Such use could result in air embolism due to residual air being drawn from the primary bag before administration of the fluid from the secondary bag is completed.

To Open

Do not remove units from overwrap until ready for use. Use all units promptly when pouch is opened.

The overwrap is a moisture barrier. The inner bag maintains the sterility of the product.

Tear pouch down side at slit and remove solution bag. 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 before preparing for administration.

Preparation for Administration

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

To Add Medication Before Solution Administration

***Warning*:** Additives may be incompatible.

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

Overdosage

In the event of fluid or solute overload during parenteral fluids, reevaluate the patient's condition and institute appropriate corrective treatment.

Storage

Avoid storage at excessive heat. It is recommended that the product be stored below 25°C.

Registration Number

015 89 24546 00.

Presentation

500 ml, 1000 ml bags.

Manufacturer

Teva Medical Ltd.,
Haorgim Street 8, Ashdod 77100