HAEMONETICS 0.9 % SODIUM CHLORIDE - sodium chloride solution
Haemonetics Corporation

HAEMONETICS 0.9 % Sodium Chloride

Description

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents. The pH is 4.5 to 7.0. Composition, osrnolarity, and ionic concentration are shown below: 0.9% Sodium Chloride Injection, USP contains 9 g/L. Sodium Chloride, USP (NaCl) with an osmolarity of 308 mOsmol/L (cale). It contains 154 mEq/L sodium and 154 mEQ/L chloride. The amount of water that can permeate from inside the container into the overlap in 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 in hemodialysis procedures.

Contraindications

None Known

Warnings

Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, servere renal insufficiency, and in clinical states in which there exist ederna with sodium retention. In patients with diminshed renal function administration of Sodium Chloride Injection, USP may result in sodium retention.

Precautions

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 must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotrophin.

Pregnancy:

Teratogenic Effects. Pregnancy Category C: Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also not known whether Sodium Chloride Injection, USP can

cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials; however, the use of sodium chloride solutions in the pediatric populations is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population. Do not administer unless solution is clear and seal is intact.

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 counter measures and save the remainder of the fluid for examination if deemed necessary.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. Parenteral drug products should be inspected visually for participate matter and discoloration prior to administration whenever solution and container permit. All injections in 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 techniques. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

500mL of 0.9% Sodium Chloride Injection, USP are contained in a flexible plastic bag and individually overwrapped. The Product Code is 441A and the NDC is 057826 441. Exposure of pharmaceutical products to beat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25 degree C): brief exposure up to 40 C does not adversely affect the product.

Directions for Use

Warnings: 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. 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 of safety. The opacity will diminish gradually. Check for minute leaks by equeezing inner bag firmly. If leaks are found, discard solutions as sterility may be impaired. If supplemental medication is desired, follow 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 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 medications port and inject. **4.** Remove container from IV pole and/or turn to an upright position. **5.** Exacuate 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.

HAEMONETICS 0.9 SODIUM CHLORIDE INJECTION, USP 500 mL

Each 100 mL contains: Sodium Chloride USP 900 mg Containing 154 mEq/L each of Sodium ion and Chloride ion pH 5.6 (range 4.5 to 7.0) Osmolarity 308 mOsm/L (Calc.) Sterile, nonpyrogenic solution. Single use container. Additives may be incompatible. Consult pharmacist if available. Use aseptic technique when introducing additives. Mix thoroughly. Do not store. Discard unused portion. **CAUTION:** Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Must not be used in series connections. Do not use unless solution is clear. Do not remove from over wrap until ready for use. The over wrap is a moisture barrier. See Directions for use. May be injected intravenously if directed by physician. Rx only.

RECOMMENDED STORAGE:

Room temperature (25 degree C/77 degree F). Avoid excessive heat. Protect from freezing.

HAEMONETICS 0.9 Sodium Chloride Injection, USP 500 mL

L352, Rev. B Product code 441A Haemonetics Corporation Braintree, MA 02184 USA Lot No. Exp. Date

HAEMONETICS Sodium Chloride Injection, USP In Plastic Container

Directions for use To Add Medication

HAEMONETICS 0.9% Sodium Chloride Injection, USP 500 mL Haemonetics Corporation Braintree, MA 02184 USA

Package Label - Directions - 1

HAEMONETICS

Sodium Chloride Injection, USP

In Plastic Container

Description

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents. The pH is 4.5 to 7.0. Composition, osmolarity, and ionic concentration are shown below:

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 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

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.

In patients with diminished renal function, administration of Sodium Chloride Injection, USP may result in sodium retention.

Precautions

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 must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotrophin.

Pregnancy: Teratogenic Effects

Pregnancy Category C: Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials; however, the use of sodium chloride 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.

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

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.

Dosage and Administration

As directed by a physician. Dosage is dependent upon 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.

All injections in 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 techniques. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

How Supplied

500mL of 0.9% Sodium Chloride Injection, USP are contained in a flexible plastic bag and individually overwrapped. The Product Code is 441A and the NDC is 057826 441.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25 C): brief exposure up to 40 C does not adversely affect the product.

Package Label - Directions - 2

Directions for Use

Warnings: 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. 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 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 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.

Package Label

HAEMONETICS®

0.9% SODIUM CHLORIDE
INJECTION, USP

500 mL

Each 100 mL contains:
Sodium Chloride USP 900 mg
Containing 154 mEq/L each of Sodium ion and Chloride ion
pH 5.6 (range 4.5 to 7.0)
Osmolarity 308 mOsm/L (Calc.)

Sterile, nonpyrogenic solution. Single use container. Additives may be incompatible. Consult pharmacist if available. Use aseptic technique when introducing additives. Mix thoroughly. Do not store. Discard unused portion.
CAUTION: Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Must not be used in series connections. Do not use unless solution is clear. Do not remove from over wrap until ready for use. The over wrap is a moisture barrier. See Directions for use. May be injected intravenously if directed by physician.

Rx only.

RECOMMENDED STORAGE: Room temperature (25°C/77°F). Avoid excessive heat. Protect from freezing.

L352, Rev. B Product code 441A

Lot No.

Haemonetics Corporation
Braintree, MA 02184 USA Exp. Date

HAEMONETICS 0.9 % SODIUM CHLORIDE
sodium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:57826-441
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	900 mg in 100 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57826-441-06	500 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076316	01/07/2013	

Labeler - Haemonetics Corporation (942344649)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Corporation		942344649	manufacture(57826-441)

Revised: 1/2013 Haemonetics Corporation