SODIUM CHLORIDE- sodium chloride injection, solution
Taro Pharmaceuticals U.S.A., Inc.

Sodium Chloride Injection USP, 0.9%

Rx only

Polypropylene Ampule

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. Each mL contains sodium chloride 9 mg. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. 0.308 m0smol/mL (calc.). The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. The pH is 5.3 (4.5 to 7.0).

Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.

The blow-fill-sealed polypropylene plastic ampule is transparent/translucent in color with a twist-off top.

CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na^+) and chloride (Cl-) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by Sodium Chloride Injection USP, 0.9% when used only as an isotonic vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in neonates and very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

PRECAUTIONS

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for

dissolving the drugs to be injected, including the route and rate of injection.

Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy Category C

Animal reproduction studies have not been conducted with Sodium Chloride Injection USP, 0.9%. It is also not known whether sodium chloride injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride injection containing additives should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness have been established in pediatric patients. However, in neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers, discard unused portion.

ADVERSE REACTIONS

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of carbohydrate, sodium chloride or fluid overload except possible in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. See **PRECAUTIONS** and **ADVERSE REACTIONS**.

DOSAGE AND ADMINISTRATION

The volume of the preparation to be used for diluting or dissolving any drug for injection, is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

Use aseptic technique for entry and withdrawal from container.

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See **PRECAUTIONS**.

HOW SUPPLIED

Sodium Chloride Injection USP, 0.9% is supplied in 5 mL single-dose (NDC 51672-3019-5) and 10 mL single-dose (NDC 51672-3019-3) polypropylene ampules in cartons containing 20 ampules.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Mfd. by: Taro Pharmaceuticals Ireland, Ltd., Roscrea, Co. Tipperary, Ireland
Dist. by: **Taro Pharmaceuticals U.S.A., Inc.,** Hawthorne, NY 10532

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51672-3019
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Chloride (UNII: 451W47IQ8X) (Sodium Chloride - UNII:451W47IQ8X)		9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51672-3019-5	20 in 1 CARTON		
1		5 mL in 1 AMPULE		
2	NDC:51672-3019-3	20 in 1 CARTON		
2		10 mL in 1 AMPULE		

Labeler - Taro Pharmaceuticals U.S.A., Inc.

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