SODIUM CHLORIDE- sodium chloride injection
Hikma Pharmaceuticals USA Inc.

0.9% Sodium Chloride Injection, USP

Rx only

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.

0.9% 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. Its chloride and sodium ion concentrations are approximately 0.154 mEq of each per milliliter and its calculated osmolality is 0.308 milliosmols per mL. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment, pH 5.3 (4.5 to 7.0).

Sodium chloride, USP occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium chloride is freely soluble in water. The empirical formula for sodium chloride is NaCl, and the molecular weight is 58.44.

The ampul is a colorless sealed sterile glass container.

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 0.9% Sodium Chloride Injection, USP 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 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

General

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

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Injection, USP. 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

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. 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 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 possibly 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

0.9% Sodium Chloride Injection, USP, is supplied in the following:

10 mL ampuls packaged in 100s (NDC 0641-1512-36)

Storage

Store at 20° - 25°C (68°-77°F), excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature]. Avoid freezing.

To report SUSPECTED ADVERSE REACTIONS, contact West-Ward Pharmaceutical Corp. at 1-877-845-0689, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For Product Inquiry call 1-877-845-0689.

Manufactured by:

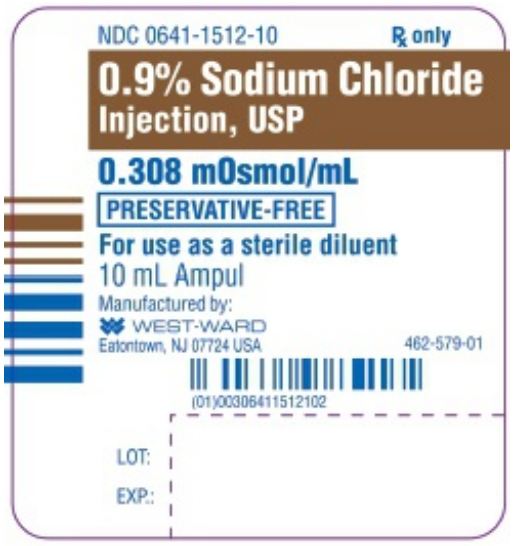
WEST-WARD
PHARMACEUTICALS
Eatontown, NJ 07724 USA

November 2011

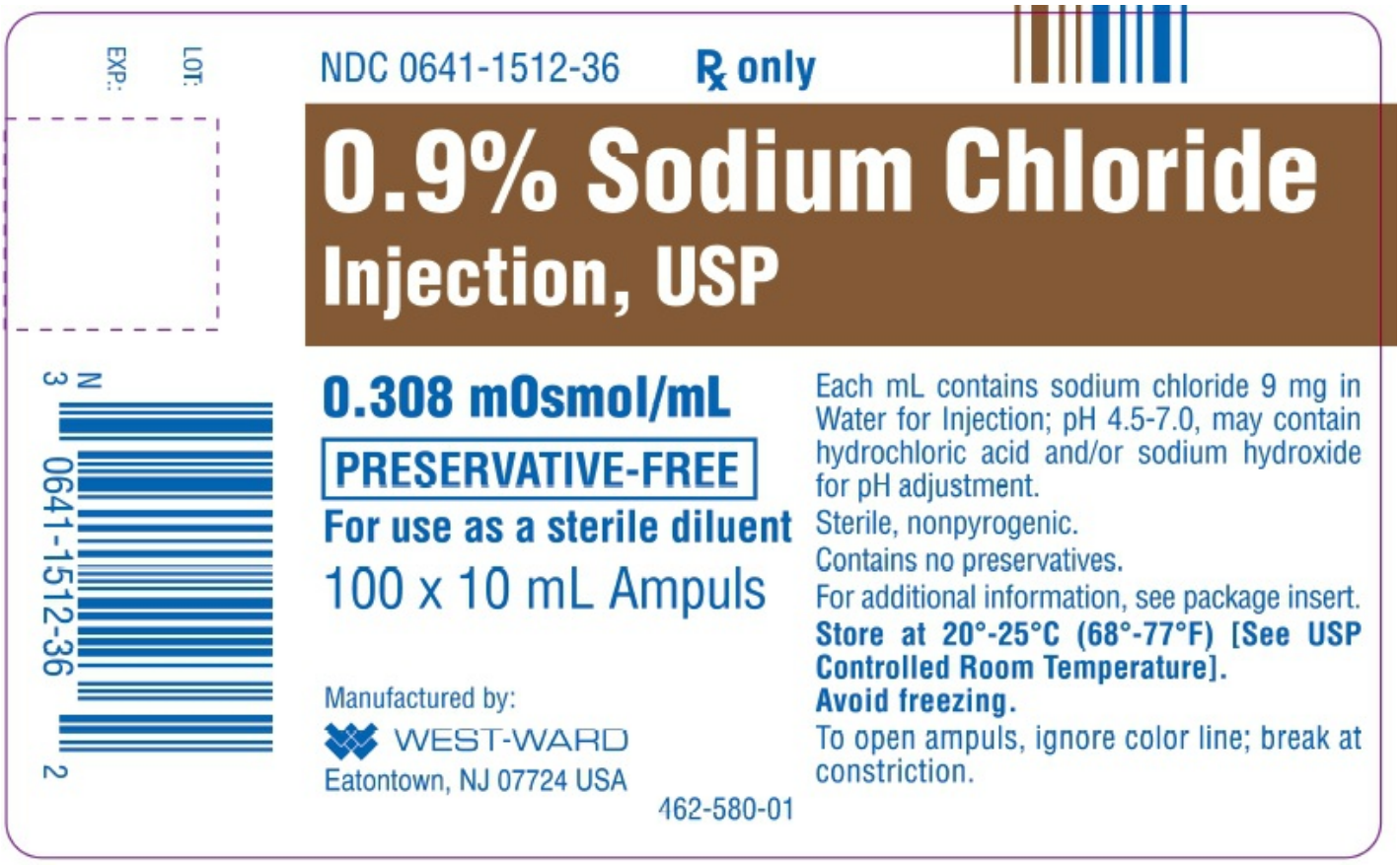
462-602-00

PRINCIPAL DISPLAY PANEL

0.9% Sodium Chloride Injection, USP
0.308 mOsmol/mL
10 mL Ampul
NDC 0641-1512-10



0.9% Sodium Chloride Injection, USP
0.308 mOsmol/mL
100 x 10 mL Ampuls
NDC 0641-1512-36



SODIUM CHLORIDE

sodium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0641-1512

Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-1512-36	100 in 1 CARTON	01/20/2012	
1	NDC:0641-1512-10	10 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201850	01/20/2012	

Labeler - Hikma Pharmaceuticals USA Inc. (946499746)

Establishment

Name	Address	ID/FEI	Business Operations
Hikma Pharmaceuticals USA Inc.		946499746	ANALYSIS(0641-1512) , LABEL(0641-1512) , MANUFACTURE(0641-1512)