SODIUM CHLORIDE- sodium chloride injection, solution
Hospira, Inc.

0.45% Sodium Chloride Injection, USP

***VisIV*™ Container** Rx only

DESCRIPTION

0.45% Sodium Chloride Injection, USP is sterile and nonpyrogenic. It is a parenteral solution containing sodium chloride in water for injection intended for intravenous administration.

Each 100 mL of 0.45% Sodium Chloride Injection, USP contains 450 mg sodium chloride in water for injection. Electrolytes per 1000 mL: sodium (Na^+) 77 mEq; chloride (Cl^-) 77 mEq. The osmolarity is 154 mOsmol/L (calc.).

The pH is 5.6 (4.5 to 7.0).

This solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only as a single-dose injection. When smaller doses are required, the unused portion should be discarded.

0.45% Sodium Chloride Injection, USP is a parenteral fluid and electrolyte replenisher.

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

Water for Injection, USP is chemically designated H_2O.

The flexible plastic container is fabricated from a clear multilayer polyolefin plastic film. Exposure to temperatures above 25°C (77°F) during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements.

Isotonic concentrations of sodium chloride are suitable for parenteral replacement of chloride losses that exceed or equal the sodium loss. Hypotonic concentrations of sodium chloride are suited for parenteral maintenance of water requirements when only small quantities of salt are desired. A hypertonic concentration of sodium chloride may be used to repair severe salt depletion syndrome.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. 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.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from two to three liters (1.0 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

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

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.

The intravenous administration of Sodium Chloride Injection, USP 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, USP may result in sodium retention.

PRECAUTIONS

General

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.

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.

Laboratory Tests

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.

DRUG INTERACTIONS

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with Sodium Chloride Injection, USP to evaluate the potential for carcinogenesis, mutagenesis or impairment of fertility.

Pregnancy:

Teratogenic Effects

Pregnancy Category C

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

Labor and Delivery

Studies have not been conducted to evaluate the effects of Sodium Chloride Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

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, USP is administered to a nursing mother.

Pediatric Use

The use of Sodium Chloride Injection, USP in pediatric patients is based on clinical practice.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids (0.45% Sodium Chloride Injection, USP) together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Geriatric Use

Clinical studies of Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

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.

In addition to the above listed adverse reactions, hyponatremia has been reported (See **Pediatric Use** section).

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate

corrective measures. (See **WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS**).

DOSAGE AND ADMINISTRATION

The dose is dependent upon the age, weight and clinical condition of the patient.

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. (See **PRECAUTIONS**).

INSTRUCTIONS FOR USE

To Open

Tear outer wrap at notch and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration. 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.

To Add Medication

(Use aseptic technique)

1. Remove blue cap from BLU-MED™ sterile medication additive port at bottom of container.
2. With a needle of appropriate length, puncture resealable additive port and inject. Withdraw needle after injecting medication.
3. Mix container contents thoroughly.
4. The additive port may be protected by an appropriate cover.

Preparation for Administration

(Use aseptic technique)

NOTE: See appropriate IV administration set Instructions for Use.

1. Close flow control clamp of administration set.
2. Remove cap from sterile administration set port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
4. Suspend container.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open clamp. Eliminate air from remainder of set.
7. Attach set to patient access device.
8. Begin infusion.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

0.45% Sodium Chloride Injection, USP is supplied in single-dose flexible plastic containers as follows:

NDC No.	Product	Fill Volume/Container size mL

0409-7985-25	0.45% Sodium Chloride Inj., USP	250/250
0409-7985-30	0.45% Sodium Chloride Inj., USP	500/500
0409-7985-48	0.45% Sodium Chloride Inj., USP	1000/1000

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.

Revised: 6/2014

EN- 3566

Hospira, Inc., Lake Forest, IL 60045 USA

IM-1674

250 mL

NDC 0409-7985-25

VisIV™ Container

0.45% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS SODIUM CHLORIDE 450 mg IN WATER FOR INJECTION. ELECTROLYTES PER 1000 mL: SODIUM 77 mEq; CHLORIDE 77 mEq.
154 mOsmol/LITER (CALC.)
pH 5.6 (4.5 to 7.0)

50

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

100

SINGLE-DOSE CONTAINER. FOR INTRAVENOUS USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] PROTECT FROM FREEZING. SEE INSERT. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS. PVC-FREE, DEHP-FREE. VisIV IS A TRADEMARK OF HOSPIRA. DO NOT REMOVE CAPS UNTIL READY FOR USE. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED.

150

200

(01)00304097985258

Rx ONLY

LATEX

5 PP

IM-1674 (7/08)

PRINTED IN USA
HOSPIRA, INC.
LAKE FOREST, IL 60045 USA

Hospira

MED

SET

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0409-7985
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (SODIUM CATION and CHLORIDE ION)	SODIUM CHLORIDE	450 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0409-7985-25	24 in 1 CASE		
1		250 mL in 1 BAG; Combination Product Type = C112160		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018090	04/04/1979	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Morton Salt, Inc.		137658043	API MANUFACTURE(0409-7985)

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