# SODIUM ACETATE

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Injection, 40 mEq in 20 mL ( 2 mEq/mL)
Plastic Vial

USPI

Reference Market: USA
AfME Markets using same as LPD: Saudi Arabia

## SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Sodium Acetate 40 mEq in 20 mL injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Acetate Injection, USP 40 mEq (2 mEq/mL) is a sterile, nonpyrogenic, *concentrated solution* of sodium acetate in water for injection. The solution is administered, after dilution, by the intravenous route as an electrolyte replenisher. It must not be administered undiluted. Each 20 mL contains 3.28 g of sodium acetate (anhydrous) which provides 40 mEq each of sodium ($Na^+$) and acetate ($CH_3COO^-$). The solution contains no bacteriostat, antimicrobial agent or added buffer. May contain acetic acid for pH adjustment; the pH is 6.5 (6.0 to 7.0). The osmolar concentration is 4 mOsmol/mL (calc).
The solution is intended as an alternative to sodium chloride to provide sodium ion ($Na^+$) for addition to large volume infusion fluids for intravenous use.
Sodium Acetate, USP (anhydrous) is chemically designated $CH_3COONa$, a hygroscopic powder very soluble in water.

The semi-rigid container is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

## 3. PHARMACEUTICAL FORM

Injection, USP for additive use only after dilution in intravenous fluids .

Plastic Vial, 40 mEq in 20 mL(2 mEq NA+ and 2 mEq $CH3COO^-$/mL)

Each 20 mL conatians 3.28 g of sodium acetate (anhydrous)

pH 6.2 (5.5 to 8.0)

The osmolar concentration is 4 mOsmol/mL (calc.).

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Sodium Acetate Injection, USP 40 mEq is indicated as a source of sodium, for addition to large volume intravenous fluids to prevent or correct hyponatremia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

### 4.2 Posology and method of administration

Sodium Acetate Injection, USP 40 mEq is administered intravenously *only after dilution in a larger volume of fluid*. The dose and rate of administration are dependent upon the individual needs of the patient. Serum sodium should be monitored as a guide to dosage. Using aseptic technique, all or part of the contents of one or more vials may be added to other intravenous fluids to provide any desired number of milliequivalents (mEq) of sodium ($Na^+$) with an equal number of acetate ($CH_3COO^-$).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. See *(section 4.4 Special warnings and precautions for use* ).

### 4.3 Contraindications

Sodium Acetate Injection, USP 40 mEq is contraindicated in patients with hypernatremia or fluid retention.

## 4.4 Special warnings and precautions for use

Sodium Acetate Injection, USP 40 mEq must be diluted before use.

To avoid sodium overload and water retention, infuse sodium-containing solutions slowly.

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 solutions containing sodium ions may result in sodium retention.

Solutions containing acetate ions should be used with great care in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

The intravenous administration of this solution (after appropriate dilution) can cause fluid and/or solute overloading resulting in dilution of other serum electrolyte concentrations, overhydration, congested states or pulmonary edema. Excessive administration of potassium free solutions may result in significant hypokalemia.

WARNING:
This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Do not administer unless solution is clear and seal is intact. Discard unused portion.

Sodium replacement therapy should be guided primarily by the serum sodium level.

Caution should be exercised in administering sodium-containing solutions to patients with severe renal function impairment, cirrhosis, cardiac failure, or other edematous or sodium-retaining states, as well as in patients with oliguria or anuria.

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

Solutions containing acetate ions should be used with caution as excess administration may result in metabolic alkalosis.

*Pediatric Use:* Safety and effectiveness have been established in the age groups infant to adolescent.

*Geriatric Use:* An evaluation of current literature revealed no clinical experience identifying differences in response 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 other drug therapy.

Sodium ions are known to be substantially excreted by the kidney, and the risk of toxic reactions 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.

### 4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

### 4.6 Fertility, pregnancy and lactation

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

### 4.7 Effects on ability to drive and use machines

Not Applicable

### 4.8 Undesirable effects

Sodium overload can occur with intravenous infusion of excessive amounts of sodium-containing solutions. See ( section 4.4 Warning and precautions for use ).

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after marketing authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions according to their local country requierements.

*To reports any side effect(s):*

- ***Saudi Arabia:***

The National Pharmacovigilance and Drug Safety Centre (NPC)
o Fax: +966-11-205-7662
o Call NPC at +966-11-2038222, Ext 2317-2356-2340
o Call Center : 19999
o E-mail: npc.drug@sfda.gov.sa
o Website: www.sfda.gov.sa/npc

### 4.9 Overdose

In the event of overdosage, discontinue infusion containing sodium acetate immediately and institute corrective therapy as indicated to reduce elevated serum sodium levels, and restore acid-base balance if necessary. See ( section 4.4 Warning and precautions for use).

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Sodium is the principal cation of extracellular fluid. It comprises more than 90% of total cations at its normal plasma concentration of approximately 140 mEq/liter. The sodium ion exerts a primary role in controlling total body water and its distribution.

Acetate ($CH_3COO^-$), a source of hydrogen ion acceptors, is an alternate source of bicarbonate ($HCO_3^-$) by metabolic conversion in the liver. This has been shown to proceed readily, even in the presence of severe liver disease.

### 5.2 Pharmacokinetic properties

Acetate ($CH_3COO^-$), a source of hydrogen ion acceptors, is an alternate source of bicarbonate ($HCO_3^-$) by metabolic conversion in the liver. This has been shown to proceed readily, even in the presence of severe liver disease.

### 5.3 Preclinical safety data

Not applicable

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Each 20 mL vial contains 3.28 g of sodium acetate (anhydrous) which provides 40 mEq each of Sodium (Na+) and acetate ($CH3COO^-$).

May contain acetic acid for pH adjustment.

This product contains aluminum that may be toxic.

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Shelf life : 24 months

### 6.4 Special precautions for storage

Keep out of the sight and reach of children.

Store below 25 ºC

### 6.5 Nature and contents of container

Sodium Acetate Injection, USP 40 mEq (2 mEq/mL) is supplied as follows:

| Unit of Sale | Concentration | Each |
|---|---|---|
| Tray Containing 25 Units | 40 mEq/20 mL | Single-dose Fliptop Vial |

| | | |
|---|---|---|
| | (2 mEq/mL) | |

Each vial is partially filled to provide air space for complete vacuum withdrawal of the contents into the intravenous container.

Keep out of the sight and reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment**.**

## 7. MARKETING AUTHORISATION HOLDER

Hospira, Inc., Lake Forest, IL 60045 USA

## 8. MANUFACUTRED BY

Hospira Inc, Rocky Mount, United States

## 9. DATE OF REVISION OF THE TEXT

January 2018

**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

**Keep all medicaments out of reach and sight of children**

**Council of Arab Health Ministers**

**Union of Arabic Pharmacists**