



SODIUM ACETATE INJECTION, USP

For Intravenous Infusion After Dilution

DESCRIPTION

Sodium Acetate Injection, USP is a sterile, nonpyrogenic, concentrated solution of sodium acetate in Water for Injection. The solution is administered after dilution by intravenous route as an electrolyte replenisher. It must not be administered undiluted.

Each mL contains:

Sodium Acetate 328 mg (4 mmol or 4 mEq) (anhydrous)

Water for Injection q.s.

Acetic acid for pH adjustment (6.0 - 7.0). The formulation contains no bacteriostat, antimicrobial agent or added buffer. Discard unused portion.

The solution is intended as an alternative to sodium chloride to provide sodium ion for addition to large volume infusion fluids for intravenous use.

Sodium acetate anhydrous is chemically designated CH_3COONa , a hygroscopic powder very soluble in water.

CLINICAL PHARMACOLOGY

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/L. The sodium ion exerts a primary role in controlling total body water and its distribution.

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

INDICATIONS AND USAGE

Sodium Acetate Injection, USP 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.

CONTRAINDICATIONS

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

WARNINGS

Sodium Acetate Injection, USP 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.

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 per kg per day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of TPN products and of the lock-flush solutions used in their administration.

PRECAUTIONS

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.

PACKAGE INSERT

Pregnancy

Teratogenic Effects: 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.

Use in Children

Sodium Acetate is not intended for pediatric use.

ADVERSE REACTIONS

Sodium overload can occur with intravenous infusion of excessive amounts of sodium-containing solutions (see **WARNINGS** and **PRECAUTIONS**).

DRUG ABUSE AND DEPENDENCE

None known.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

For management of a suspected drug overdose, contact your Regional Poison Control Centre.

In the event of overdose, 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 **WARNINGS**, **PRECAUTIONS** and **ADVERSE REACTIONS**).

DOSAGE AND ADMINISTRATION

Sodium Acetate Injection, USP is administered intravenously **only after dilution in a larger volume of intravenous fluids**. 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 with an equal number of acetate.

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

DIRECTIONS FOR DISPENSING FROM MAXIVIAL[®] Pharmacy Bulk Package:

Sodium Acetate Injection, USP is available in a **single-use** vial for pharmacy use only, referred to as a Maxivial[®]. Like the single dose vial, **Maxivial[®] is not for direct infusion**. Maxivial[®] comes with a hanging vial label and should be suspended as a unit in a laminar flow hood. Entry into the vial must be made with a sterile transfer set or other sterile dispensing device and contents dispensed in aliquots using aseptic technique (see **DOSAGE AND ADMINISTRATION**).

PACKAGE INSERT

Use of syringe/needle is not recommended as it may cause leakage. **Any unused portion should be discarded within 24 hours after initial entry.**

AVAILABILITY OF DOSAGE FORMS

Sodium Acetate Injection, USP is supplied in single-dose, flip-top vials (C3250), in boxes of 25, and Maxivial[®] Pharmacy Bulk Packages (C32B1).

Product Number	Sodium Acetate Content (%)	Na ⁺ mmol/mL or mEq/mL	CH ₃ COO ⁻ mmol/mL or mEq/mL	mOsmol/mL	Fill Volume (mL)
C3250	32.8	4	4	8	50
C32B1	32.8	4	4	8	100

Store between 15 °C – 30 °C. Do not permit to freeze.



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