PRESCRIBING INFORMATION

SODIUM ACETATE INJECTION, USP

Sterile solution contains Sodium Acetate (anhydrous) 328 mg / mL

[4 mmol or 4 mEq of sodium ions (Na+)]

Total osmolar concentration 8 mOsmol per mL

100 mL Pharmacy Bulk Package and 50 mL single dose vial —Not for Direct Infusion

Electrolyte Replenisher

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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 of sodium ions (Na+) anhydrous]

Water for Injection……. q.s.

Acetic acid for pH adjustment (6.0 - 7.0). Total osmolar concentration 8 mOsmol per mL. 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 addition to large volume infusion fluids for intravenous use.

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

ACTION AND 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 CLINICAL USE

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.

WARNING: This product contains aluminum which 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.

This product contains no more than 300 mcg/L of aluminum.

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.

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).

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

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 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 discolouration prior to administration, whenever solution and container permit.

50 mL Single-dose container is designed for use with a single patient as a single injection/infusion. Discard unused portion.

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 use 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).

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

AVAILABILITY OF DOSAGE FORMS

Sodium Acetate Injection, USP is supplied in USP type I glass clear vials, closed with Bromobutyl grey rubber closures and sealed with aluminum, flip-top seals, in boxes of 25, and Maxivial™ Pharmacy Bulk Packages.

	Single use vial	**Maxivial™ Pharmacy Bulk Packages**
Sodium Acetate Content (%)	32.8	32.8
Na^+ mmol/mL or mEq/mL	4	4
CH_3COO^- mmol/mL or mEq/mL	4	4
mOsmol/mL	8	8
Fill Volume (mL)	50	100

STORAGE AND STABILITY RECOMMENDATIONS

Store at 15 °C to 30 °C. Do not freeze.

If you want more information about Sodium Acetate Injection, USP:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (https://www.fresenius-kabi.com/en-ca), or by calling 1-877-821-7724.

This Prescribing Information was prepared by:

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