SODIUM ACETATE- sodium acetate injection, solution, concentrate
MILLA PHARMACEUTICALS INC.

SODIUM ACETATE

Injection, USP

40 mEq (2 mEq/mL)

FOR ADDITIVE USE ONLY AFTER DILUTION

IN INTRAVENOUS FLUIDS.

Glass Fliptop Vial

Rx only

DESCRIPTION

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 ($CH3COO^-$). 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.

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/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.

INDICATIONS AND USAGE

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.

CONTRAINDICATIONS

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

WARNINGS

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.

PRECAUTIONS

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.

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.

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.

ADVERSE REACTIONS

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

OVERDOSAGE

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 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 ***PRECAUTIONS***.

HOW SUPPLIED

Sodium Acetate Injection, USP 40 mEq is supplied as follows:

		Total Amounts		
NDC No.	**Fill Volume**	**Na +**	**Acetate**	**Concentration**
71357-002-01-Glass Fliptop Vial 71357-002-10-Case Containing 10 Units	20 mL	40 mEq	40 mEq	16.4%

Sodium Acetate Injection, USP 40 mEq per 20 mL vials are suppled as 10 vials per carton, with a single package insert.

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

Store at 20° to 25ºC (68° to 77ºF). [See USP Controlled Room Temperature.]

ALSO AVAILABLE AS

Sodium Acetate Injection, USP is also supplied in Pharmacy Bulk Packages as follows:

		Total Amounts		
NDC No.	**Fill Volume**	**Na +**	**Acetate**	**Concentration**
71357-007-01– Glass Fliptop Vial 71357-007-10 – Case Containing 10 Units	50 mL	100 mEq	100 mEq	16.4%
71357-008-01– Glass Fliptop Vial 71357-008-10 – Case Containing 10 Units	100 mL	200 mEq	200 mEq	16.4%
71357-009-01– Glass Fliptop Vial 71357-009-10 – Case Containing 10 Units	100 mL	400 mEq	400 mEq	32.8%

Manufactured by:

S.M. Farmaceutici SRL

Tito – 85050, Italy

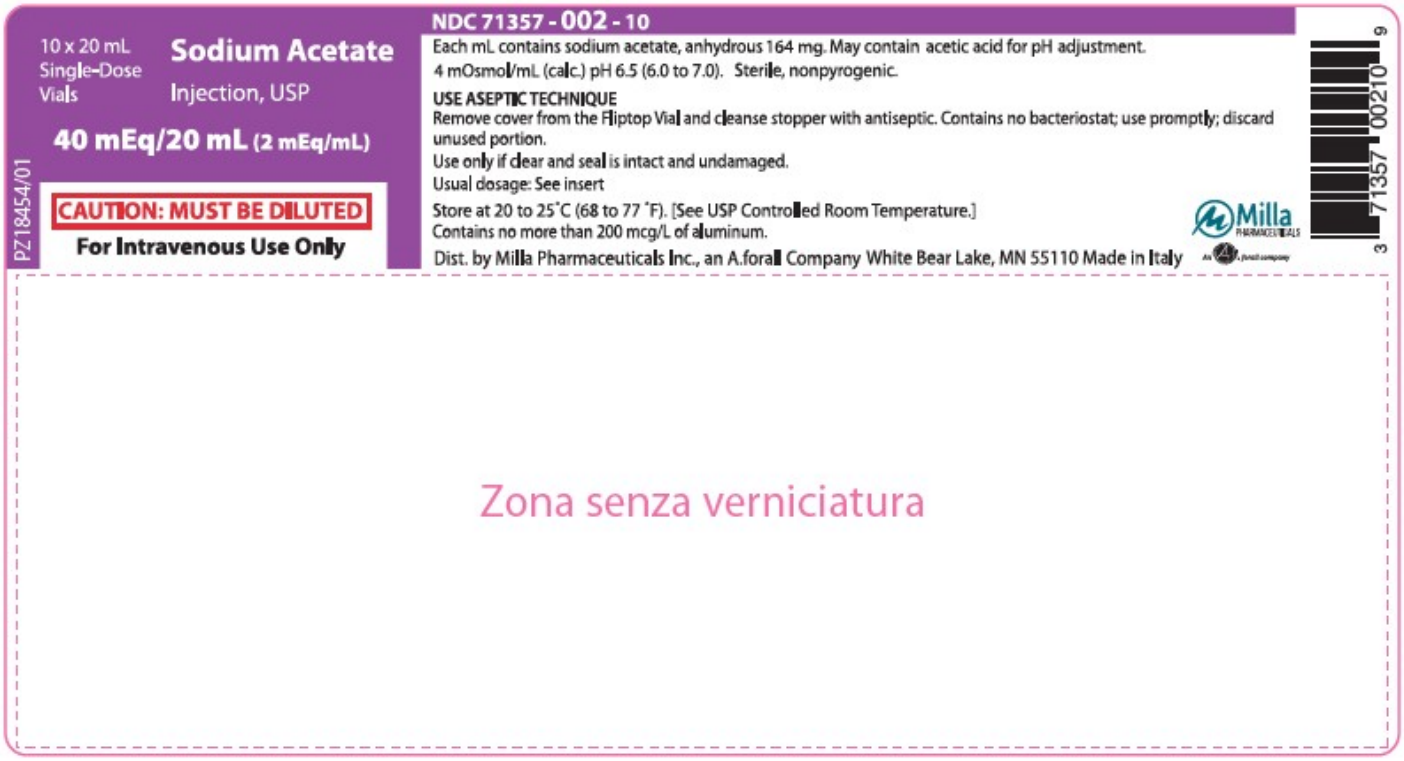
Distributed by:

Milla Pharmaceuticals Inc., an A.forall Company
White Bear Lake, MN 55110

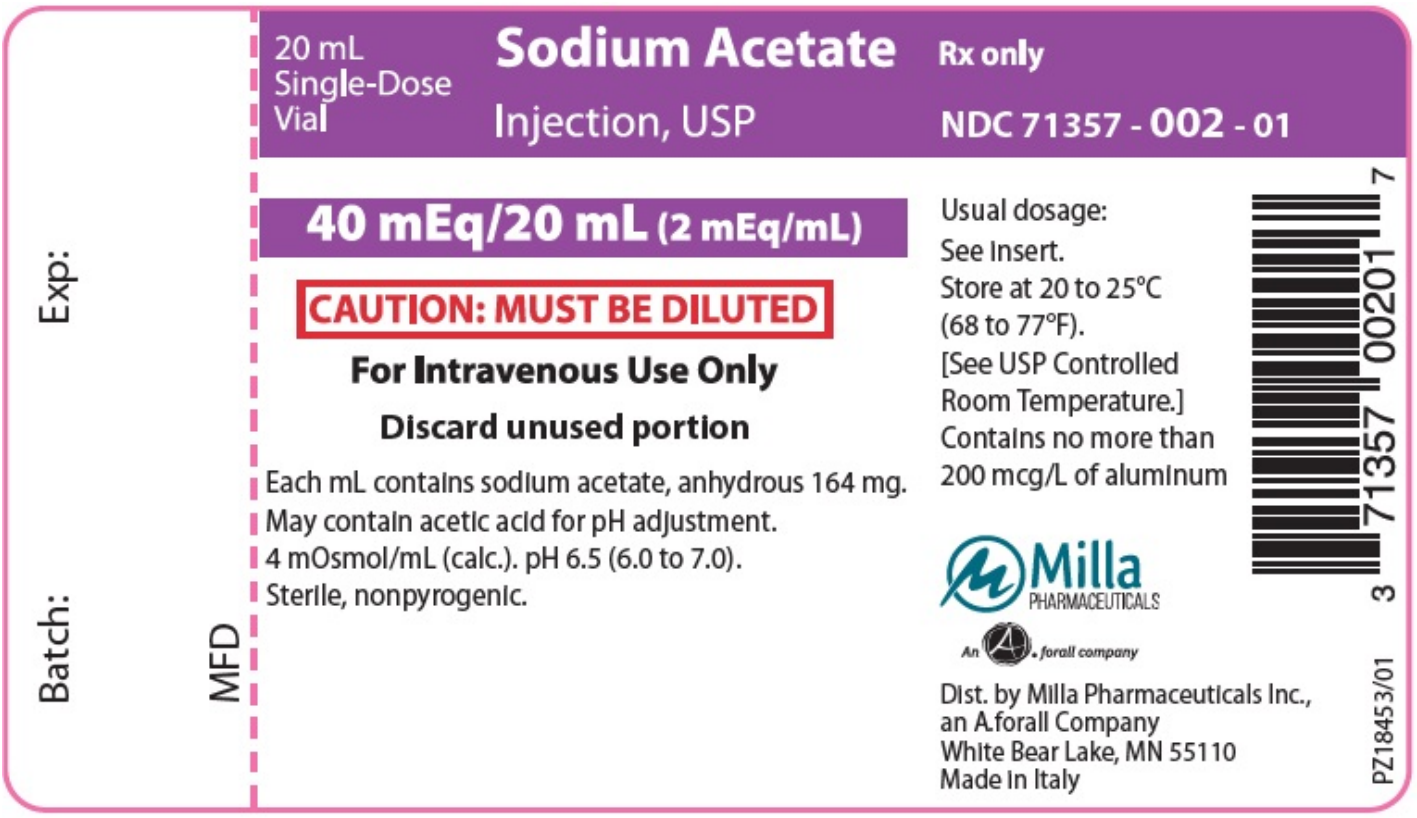
Revised: June 2024

PRINCIPAL DISPLAY PANEL

Sodium Acetate Injection, USP 40 mEq/20 mL NDC 71357-002-10 Carton Label



Sodium Acetate Injection, USP 40 mEq/20 mL NDC 71357-002-01 vial Label



SODIUM ACETATE

sodium acetate injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71357-002
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM ACETATE (UNII: 4550K0SC9B) (ACETATE ION - UNII:569DQM74SC, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM ACETATE ANHYDROUS	164 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ACETIC ACID (UNII: Q40Q9N063P)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71357-002-10	10 in 1 CASE	01/17/2025	

1	NDC:71357-002-01	20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214805	01/17/2025	

Labeler - MILLA PHARMACEUTICALS INC. (119319487)

Registrant - MILLA PHARMACEUTICALS, INC. (080563277)

Establishment

Name	Address	ID/FEI	Business Operations
S.M. FARMACEUTICI SRL		430188286	manufacture(71357-002)

Revised: 1/2025 MILLA PHARMACEUTICALS INC.