SODUM ACETATE- sodium acetate injection, solution, concentrate
American Regent, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SODIUM ACETATE FOR INJECTION, USP CONCENTRATE

Rx Only

32.8% (4 mEq/mL) 7997 mOsmol/L
Calculated pH (6.0-7.0) (8 mOsmol/mL)

CAUTION: FOR INTRAVENOUS USE ONLY
MUST BE DILUTED PRIOR TO ADMINISTRATION

DESCRIPTION

Sodium Acetate for Injection, USP **CONCENTRATE**, 4 mEq/mL, is a sterile, nonpyrogenic, concentrated solution of Sodium Acetate ($C_2H_3NaO_2$) in Water for Injection. It must be diluted prior to administration.

Each 50 mL vial contains 16.4 grams of Sodium Acetate (anhydrous) which provides 200 mEq each of Sodium (Na^+) and Acetate (CH_3COO^-).

The pH is adjusted with acetic acid and the solution contains no bacteriostatic agent or other preservative.

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. Unused portion should be discarded.

CLINICAL PHARMACOLOGY

Sodium is the principal cation of extracellular fluids. The sodium ion exerts a primary role in controlling total body water and its distribution. The acetate ion is completely metabolized in the body, providing a source of hydrogen ion acceptors.

INDICATIONS AND USAGE

Sodium Acetate for Injection, USP **CONCENTRATE** is indicated as a source of sodium 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 for Injection, USP **CONCENTRATE** is contraindicated in patients with HYPERNATREMIA.

WARNINGS

Sodium Acetate for Injection, USP **CONCENTRATE** must be diluted before use. To avoid sodium overload and water retention, infuse sodium containing solutions slowly. Do not use unless solution is clear and seal is intact.

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

Sodium replacement therapy should be guided primarily by serum sodium level. Use with caution in patients with renal impairment, cirrhosis, cardiac failure or other edematous or sodium retaining states.

Use in Pregnancy

Safety for use in pregnancy has not been established. Use of sodium acetate in women of childbearing potential requires that anticipated benefits be weighed against possible hazards.

ADVERSE REACTIONS

Sodium overload can occur with intravenous infusion of excessive amounts of sodium containing compounds. See WARNINGS.

DOSAGE AND ADMINISTRATION

Sodium Acetate for Injection, USP **CONCENTRATE** (4 mEq/mL), is administered intravenously only after dilution.

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. Withdraw the calculated volume aseptically and transfer to appropriate intravenous fluids to provide the desired number of milliequivalents (mEq) of sodium (Na^+) with an equal number of milliequivalents of acetate (CH_3COO^-).

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

HOW SUPPLIED

Sodium Acetate for Injection, USP **CONCENTRATE** (4 mEq /mL)

NDC 0517-5023-25 50 mL Single Dose Vial packed in boxes of 25

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) (See USP Controlled Room Temperature).

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967

IN5023
Rev. 11/05

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PRINCIPLE DISPLAY PANEL - 50 mL Container

NDC 0517-5023-25

SODIUM ACETATE
FOR INJECTION, USP
CONCENTRATE

200 mEq/50 mL
(4 mEq/mL)

50 mL SINGLE DOSE VIAL

FOR IV USE AFTER DILUTION

Rx Only

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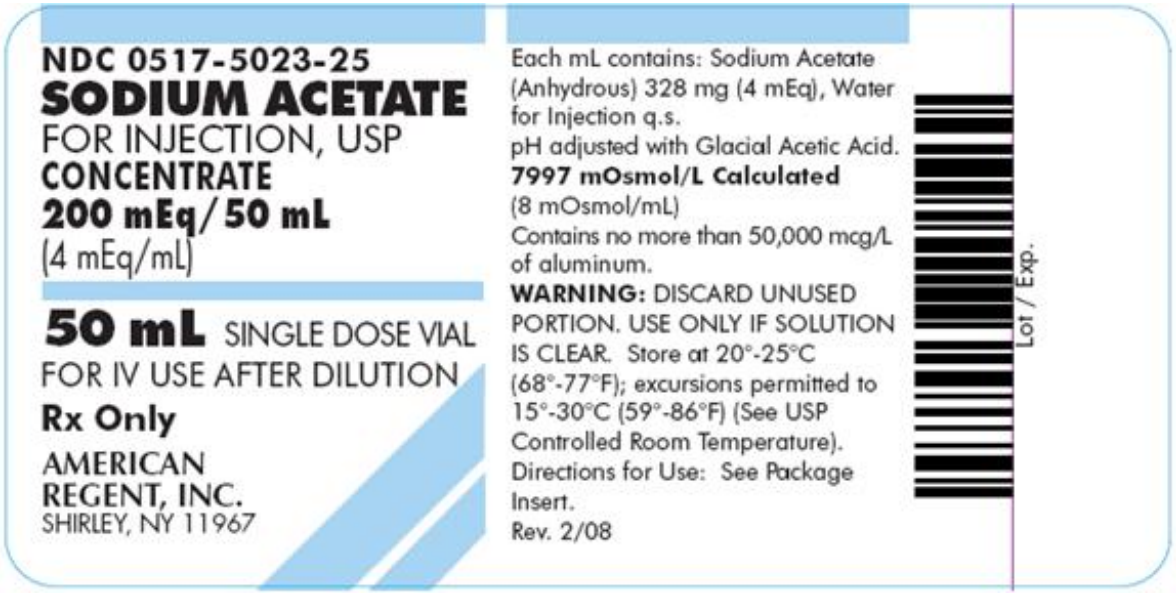
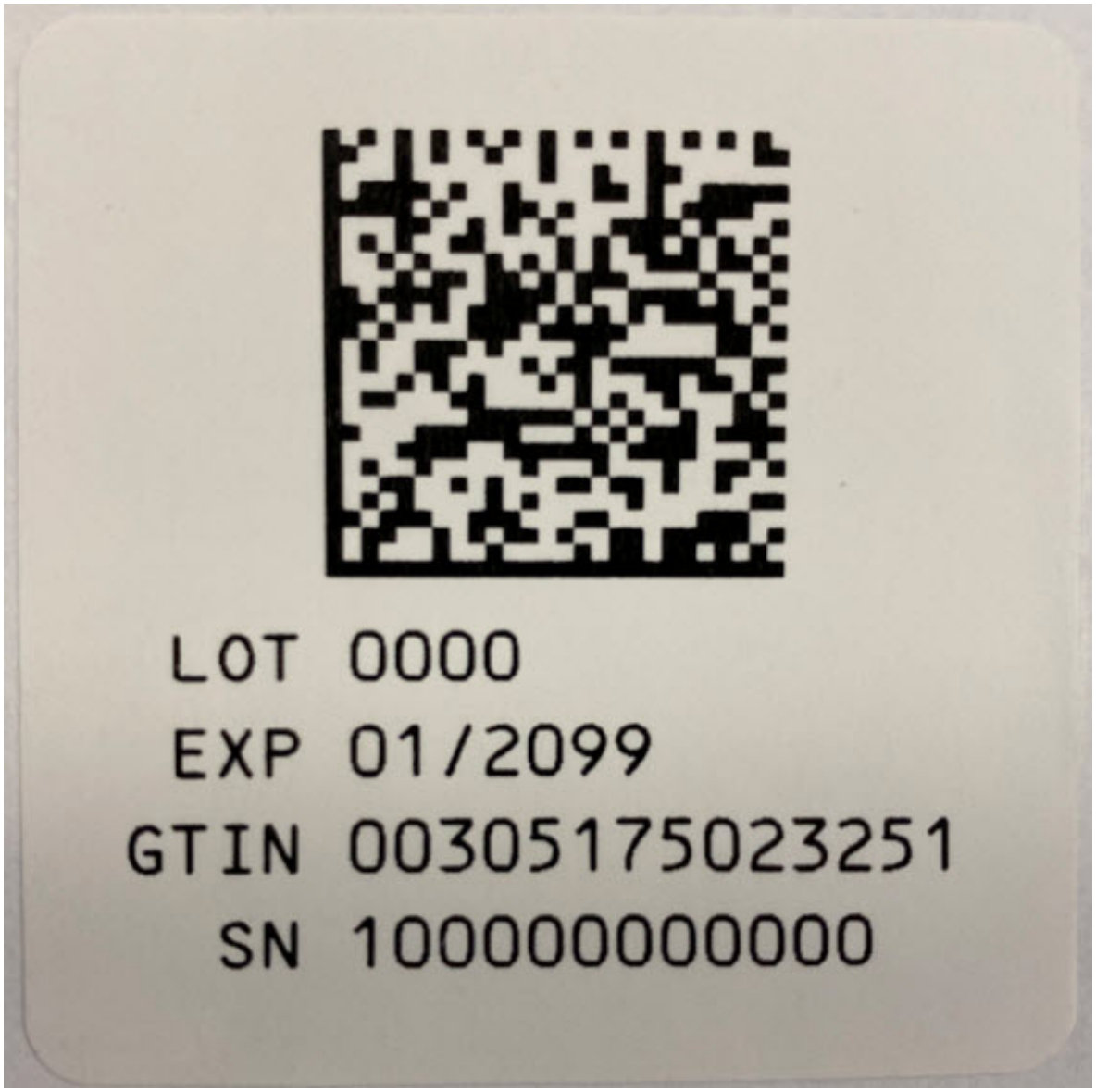
REGENT, INC.
SHIRLEY, NY 11967



Serialization Label



SODUM ACETATE

sodium acetate injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-5023
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM ACETATE ANHYDROUS (UNII: NVG71ZZ7P0) (ACETATE ION - UNII:569DQM74SC, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM ACETATE ANHYDROUS	328 mg in 1 mL

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

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0517-5023-25	25 in 1 TRAY	09/30/1990	
1		50 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
UNAPPROVED DRUG OTHER		09/30/1990	

Labeler - American Regent, Inc. (002033710)

Establishment

Name	Address	ID/FEI	Business Operations
American Regent, Inc.		002033710	ANALYSIS(0517-5023) , MANUFACTURE(0517-5023)

Revised: 1/2020 American Regent, Inc.