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

SODIUM ACETATE

Injection, USP

Pharmacy Bulk Package. Not for Direct Infusion

FOR ADDITIVE USE ONLY AFTER DILUTION

IN IV FLUIDS.

Glass Fliptop Vial

Rx only

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 the intravenous route as an electrolyte replenisher. It must not be administered undiluted. Each mL of 2 mEq/mL product contains 164 mg of sodium acetate (anhydrous) which provides 2 mEq each of sodium (Na^+) and acetate (CH_3COO^-). Each mL of 4 mEq/mL product contains 328 mg of sodium acetate (anhydrous) which provides 4 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.) in 2 mEq/mL product and 8 mOsmol/mL (calc.) in 4 mEq/mL product; specific gravity 1.081(2 mEq/mL) and 1.1511 (4 mEq/mL).

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.

A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion.

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^-) is a hydrogen ion acceptor. It also serves as an alternate source of bicarbonate (HCO_3^-) by metabolic conversion in the liver. This conversion 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.

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 Injection, USP. It is also not known whether Sodium Acetate Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Acetate Injection, USP 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 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, transfer the desired amount to other intravenous fluids to provide the appropriate number of milliequivalents (mEq) of sodium acetate.

Sodium Acetate Injection, USP in the Pharmacy Bulk Package is designed for use with manual, gravity flow operations and automated compounding devices for preparing intravenous nutritional admixtures. Admixtures must be stored under refrigeration and used within 24 hours after compounding.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. (See ***PRECAUTIONS***.)

Directions for Dispensing From Pharmacy Bulk Package

The Pharmacy Bulk Package is for use in the Pharmacy Admixtures Service only. For hanger application, peel off the paper liner from both ends of the tape hanger to expose ¾ inch long adhesive portions. Adhere each end to the label on the bottle. The vials should be suspended as a unit in the laminar flow hood.

A single entry through the vial closure should be made with a sterile dispensing set or transfer device. Transfer individual doses to appropriate intravenous infusion solutions. Use of a syringe with needle is not recommended as it may cause leakage and multiple entries will increase the potential of microbial and particulate contamination.

The above process should be carried out under a laminar flow hood using aseptic technique.

Discard any unused portion within 4hours after initial closure entry.

HOW SUPPLIED

Sodium Acetate Injection, USP is 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	100 mL	200 mEq	200 mEq 16.4%

Containing 10 Units 71357-009-01 – Glass Fliptop Vial 71357-009-10 – Case Containing 10 Units	100 mL	400 mEq	400 mEq	32.8%

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

Manufactured by:

S.M. Farmaceutici SRL

Tito – 85050, Italy

Distributed by:

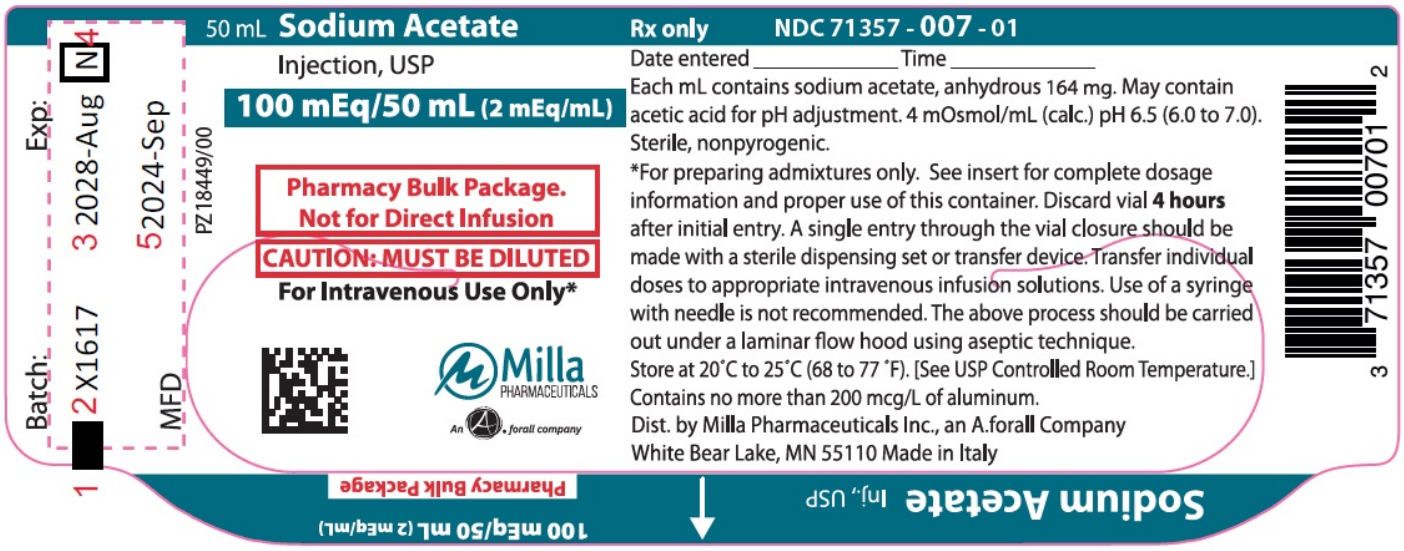
Milla Pharmaceuticals Inc., an A.forall Company

White Bear Lake, MN 55110

Revised: June 2024

PRINCIPAL DISPLAY PANEL

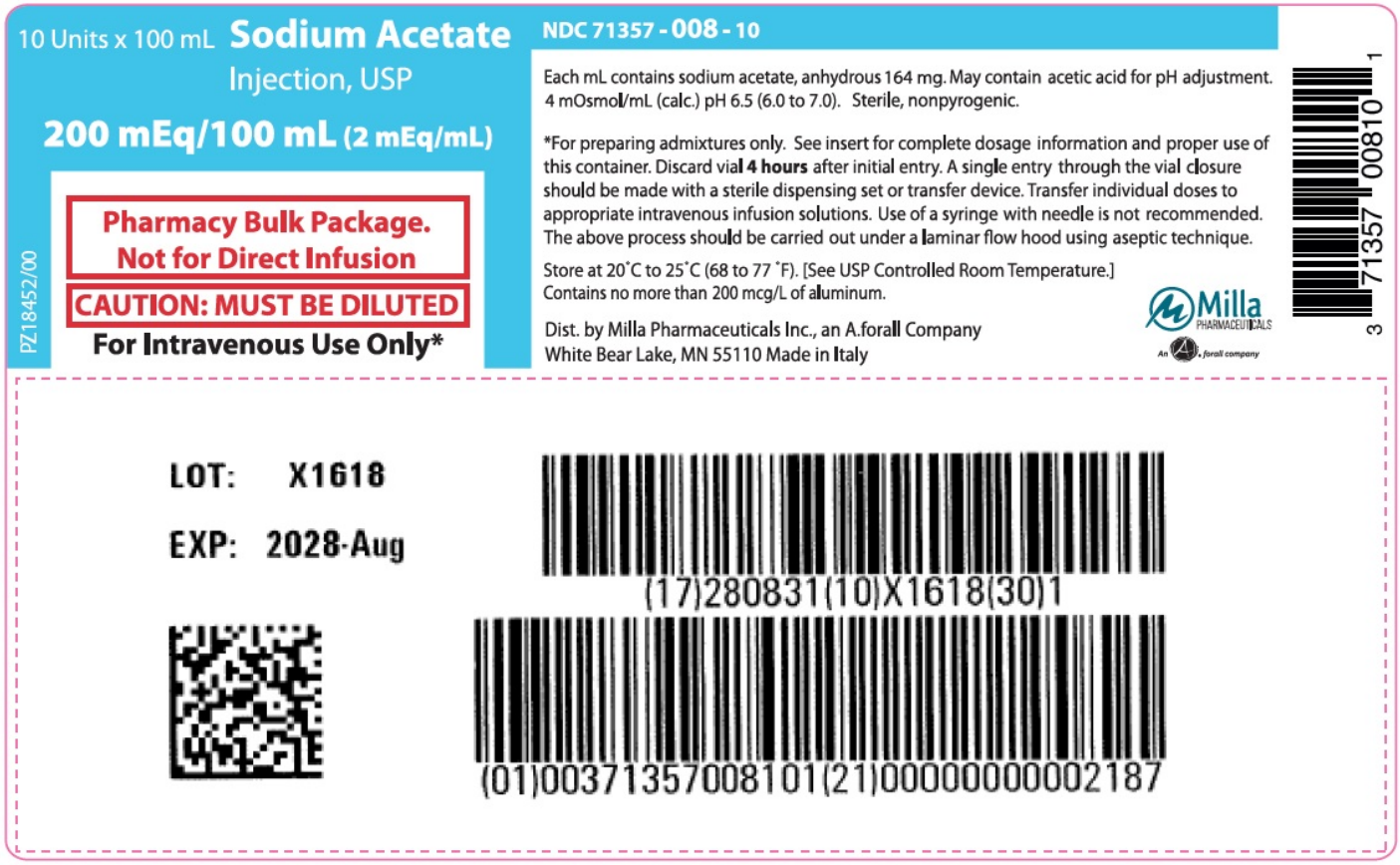
Sodium Acetate Injection, USP 100 mEq/50mL - 71357-007-01 - Vial Label



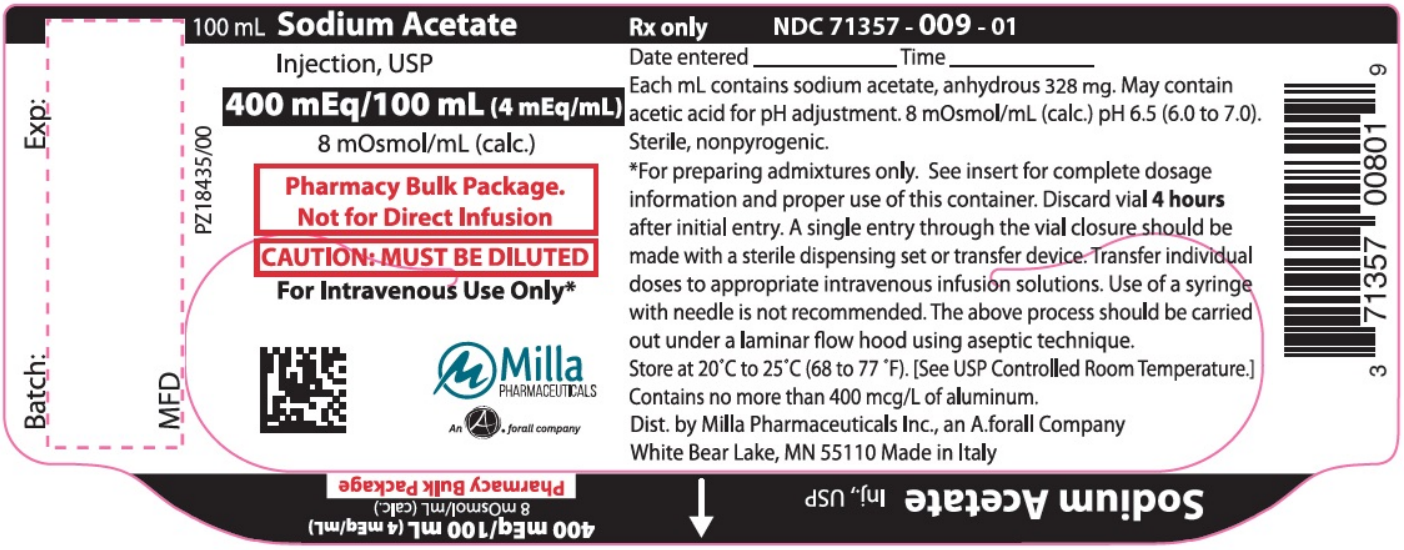
Sodium Acetate Injection, USP 100 mEq/50mL - 71357-007-10 - Carton Label

Sodium Acetate Injection, USP 200 mEq/100mL - 71357-008-01 - Vial Label

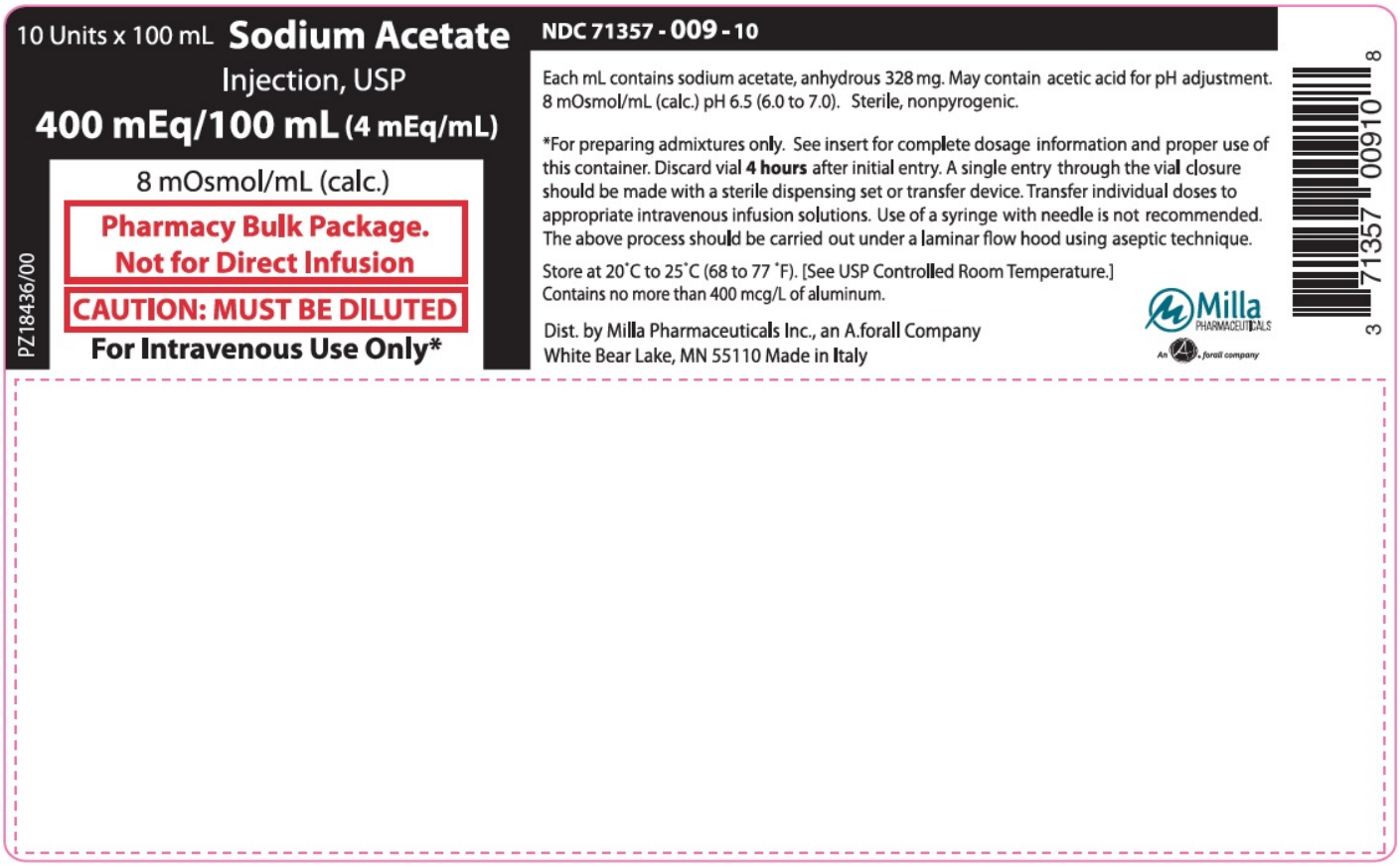
Sodium Acetate Injection, USP 200 mEq/100mL - 71357-008-10 - Carton Label



Sodium Acetate Injection, USP 400 mEq/100mL - 71357-009-01 - Vial Label



Sodium Acetate Injection, USP 400 mEq/100mL - 71357-009-10 - Carton Label



SODIUM ACETATE

sodium acetate injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71357-007
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:71357-007-10	10 in 1 CASE	10/25/2024	
1	NDC:71357-007-01	50 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214805	10/25/2024	

SODIUM ACETATE

sodium acetate injection, usp, 200 meq/100 ml injection, solution, concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71357-008
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM ACETATE (UNII: 4550K0SC9B) (ACETATE ION - UNII:569DQM74SC)	SODIUM ACETATE	200 meq in 100 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:71357-008-10	10 in 1 CASE	10/25/2024	
1	NDC:71357-008-01	100 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214805	10/25/2024	

SODIUM ACETATE

sodium acetate injection, usp, 400 meq/100 ml injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71357-009
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM ACETATE (UNII: 4550K0SC9B) (ACETATE ION - UNII:569DQM74SC)	SODIUM ACETATE	400 meq in 100 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:71357-009-10	10 in 1 CASE	12/06/2024	
1	NDC:71357-009-01	100 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA214805	12/06/2024	

Labeler - MILLA PHARMACEUTICALS INC. (119319487)

Registrant - MILLA PHARMACEUTICALS, INC. (080563277)

Establishment

Name	Address	ID/FEI	Business Operations
S.M. FARMACEUTICI SRL		430188286	manufacture(71357-007, 71357-008, 71357-009)

Revised: 12/2024 MILLA PHARMACEUTICALS INC.