SODIUM CHLORIDE- sodium chloride injection, solution
Nexus Pharmaceuticals LLC

0.9% Sodium Chloride

Injection, USP

Preservative-Free

Rx only

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. Each mL contains sodium chloride 9 mg. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. 0.308 mOsmol/mL (calc.). 0.9% Sodium Chloride Injection, USP contains no preservatives. The solution may contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH 5.3 (4.5 to 7.0).

Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.

The glass container is a Type I borosilicate glass and meets the requirements of the powdered glass test according to the USP standards.

CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by 0.9% Sodium Chloride Injection, USP when used only as an isotonic vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in neonates and very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

PRECAUTIONS

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.

Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

*Pregnancy:*Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Injection, USP. It is also not known whether sodium chloride injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium chloride injection containing additives should be given to a pregnant woman only if clearly needed.

*Pediatric Use:*The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for single or multiple entry and withdrawal from all containers. When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers, discard unused portion.

ADVERSE REACTIONS

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of carbohydrate, sodium chloride or fluid overload except possibly in neonates or very small infants. In the event these should occur, re-evaluate the patient and institute appropriate corrective measures. See **PRECAUTIONS**and **ADVERSE REACTIONS**.

DOSAGE AND ADMINISTRATION

The volume of the preparation to be used for diluting or dissolving any drug for injection, is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer. This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

0.9% Sodium Chloride Injection, USP is supplied in the following:

Unit of Sale	Concentration
NDC 14789-133-05 10 mL Single-dose glass vials in carton of 25	0.9% (10 mL)
NDC 14789-134-05 20 mL Single-dose glass vials in carton of 25	0.9% (20 mL)

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

Manufactured in the USA by:
Nexus Pharmaceuticals, LLC
Lincolnshire, IL 60069
SCIPIR001
Revised: 12/2022

Principal Display Panel – 10 mL Carton Label

NDC 14789-133-05

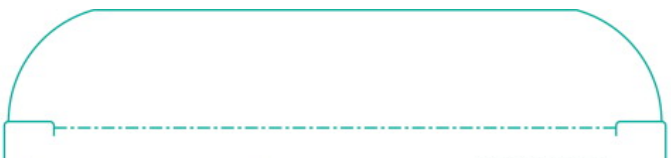
Rx Only

0.9% Sodium Chloride
Injection, USP

For Use as a Sterile Diluent

Contains 25 x 10 mL Single-dose Vials

NEXUS
PHARMACEUTICALS



NDC 14789-133-05 Rx Only

0.9% Sodium Chloride Injection, USP

For Use as a Sterile Diluent

Contains 25 x 10 mL Single-dose Vials

NEXUS PHARMACEUTICALS

Each mL contains: Sodium Chloride, 9 mg. May contain HCl and/or NaOH for pH adjustment.

Sterile, nonpyrogenic. 0.308 mOsmol/mL (calc)

Mix thoroughly after dilution. Use only if clear and seal is intact and undamaged. Preservative-free. Use promptly. Discard unused portion.

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

NDC 14789-133-05 Rx Only

0.9% Sodium Chloride Injection, USP

For Use as a Sterile Diluent

Contains 25 x 10 mL Single-dose Vials

NEXUS PHARMACEUTICALS

SCICT01R01

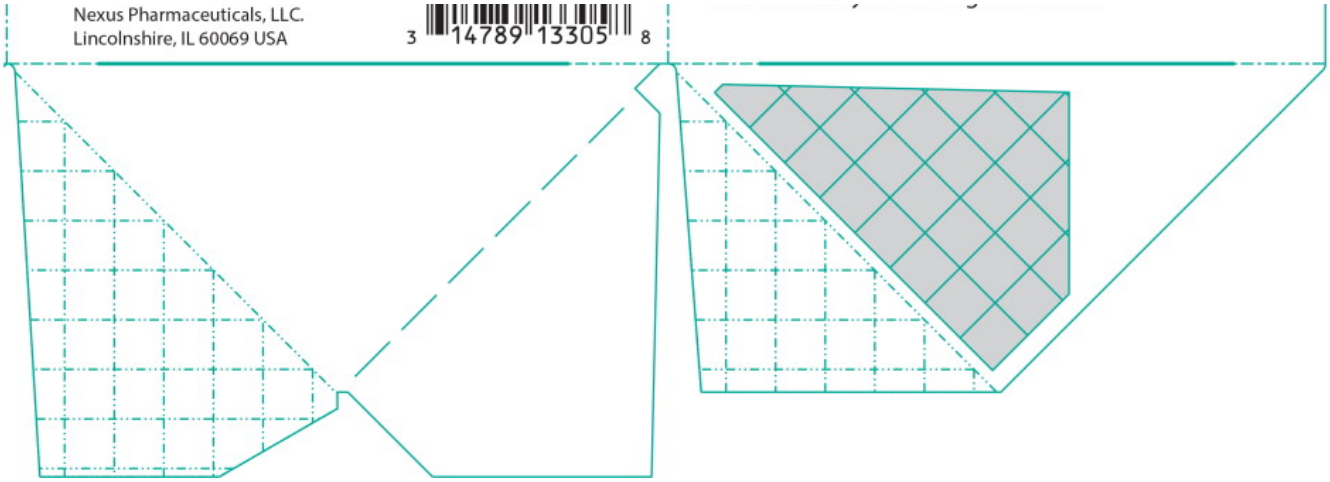
NEXUS PHARMACEUTICALS

Manufactured in the USA by:

USE ASEPTIC TECHNIQUE
Remove cover from vial and cleanse stopper with antiseptic

With Sterile Syringe and Needle:

1. Aspirate desired portion of vial contents and add to suitable container
2. Discard any remaining fluid in vial



Principal Display Panel – 10 mL Vial Label

NDC 14789-133-07

Rx Only

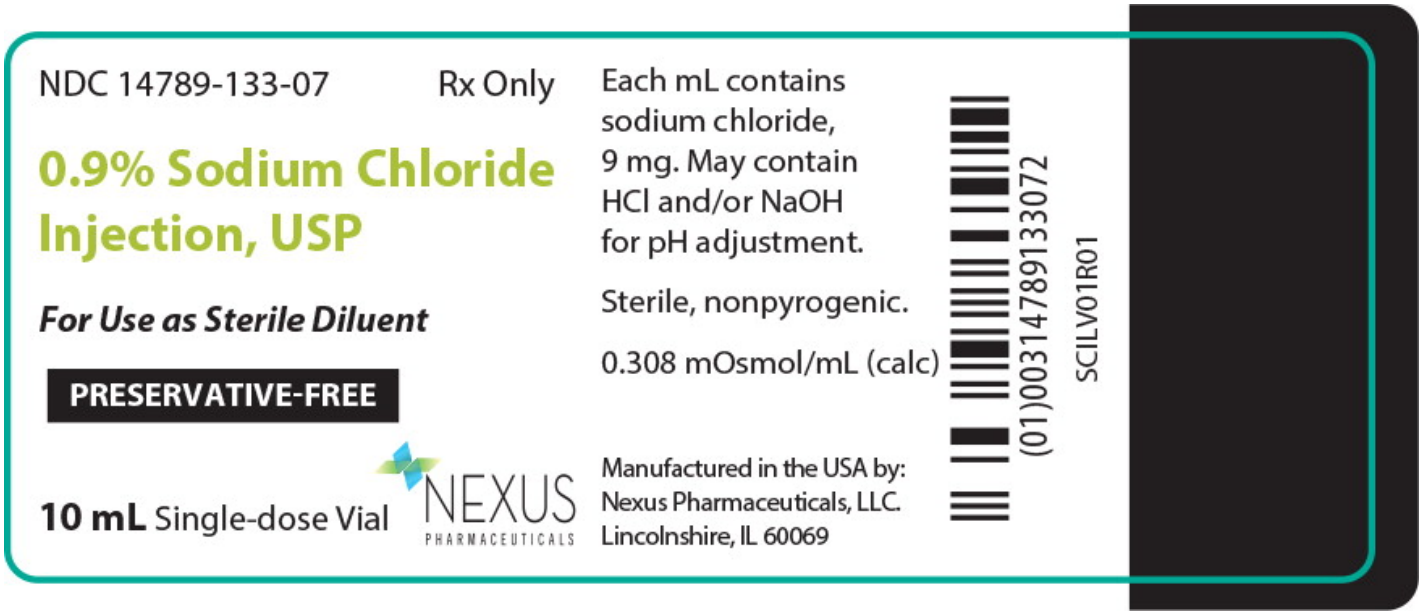
0.9% Sodium Chloride
Injection, USP

For Use as Sterile Diluent

PRESERVATIVE-FREE

10 mL Single-dose Vial

NEXUS
PHARMACEUTICALS



Principal Display Panel – 20 mL Carton Label

NDC 14789-134-05

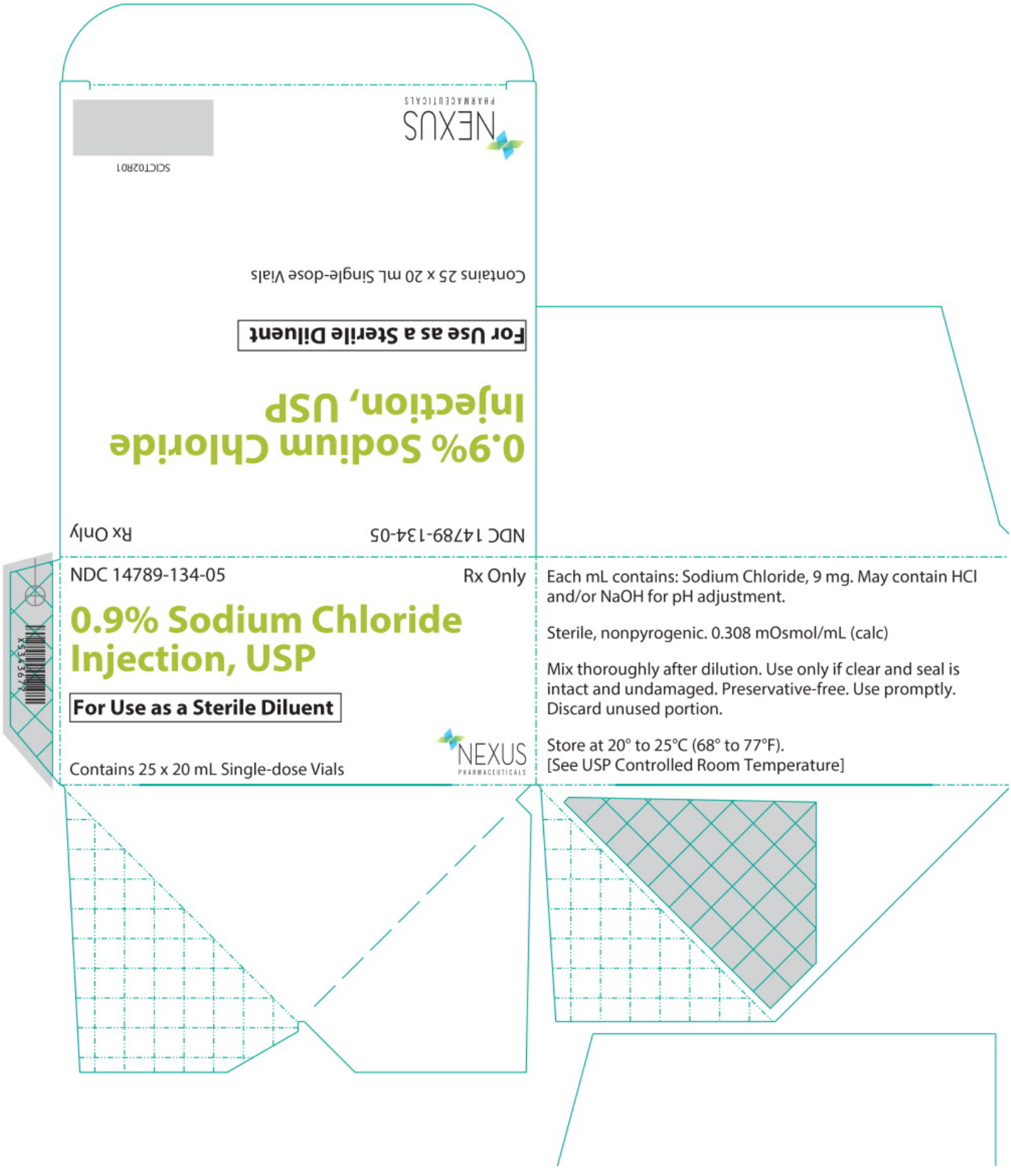
Rx Only

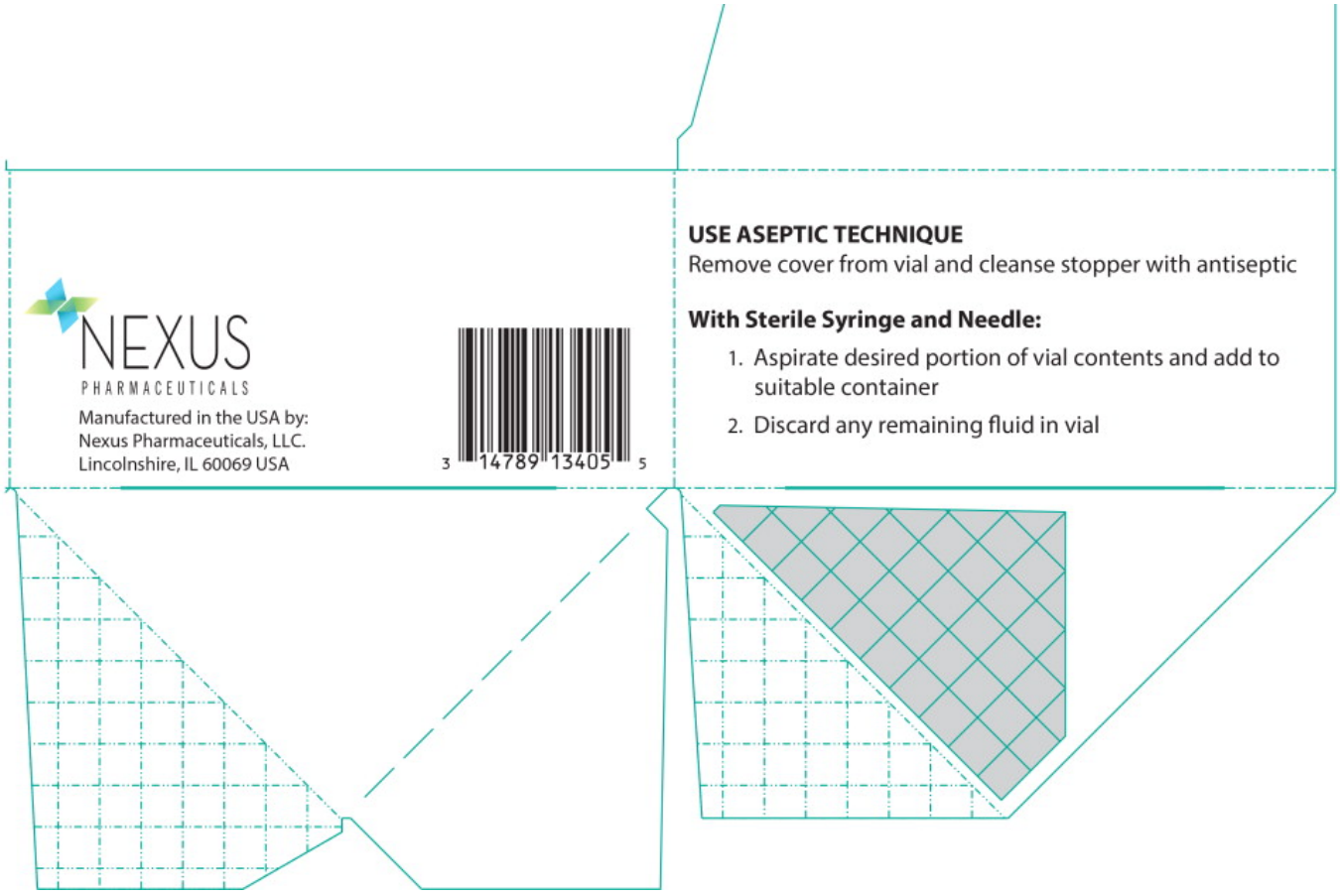
0.9% Sodium Chloride
Injection, USP

For Use as a Sterile Diluent

Contains 25 x 20 mL Single-dose Vials

NEXUS
PHARMACEUTICALS





Principal Display Panel – 20 mL Vial Label

NDC 14789-134-07

Rx Only

0.9% Sodium Chloride Injection, USP

For Use as Sterile Diluent

PRESERVATIVE-FREE

20 mL Single-dose Vial

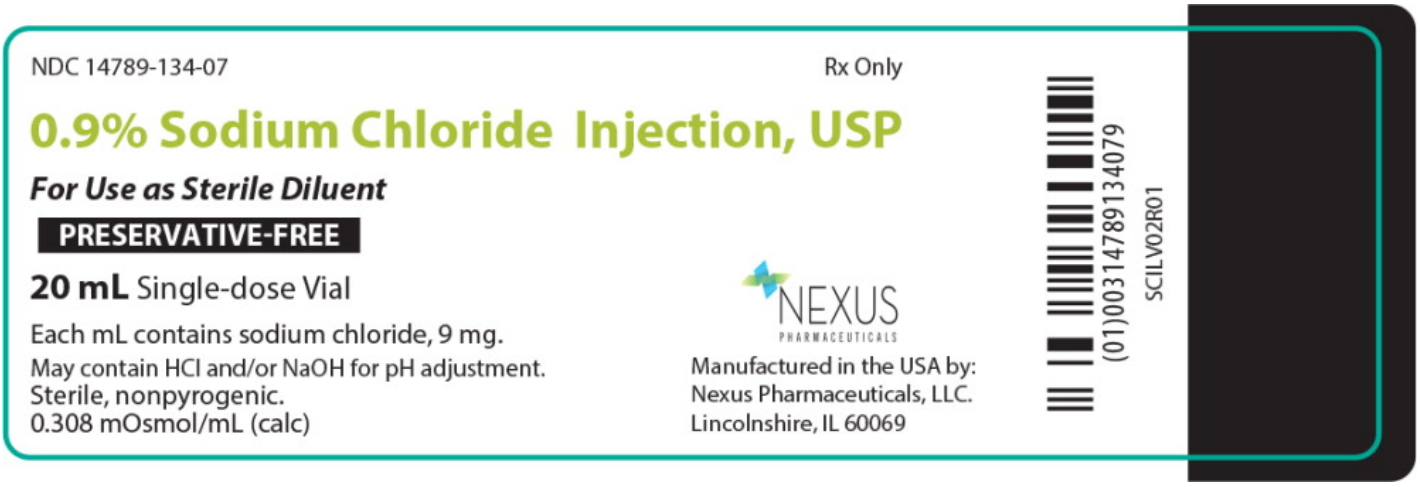
Each mL contains sodium chloride, 9 mg.

May contain HCl and/or NaOH for pH adjustment.

Sterile, nonpyrogenic.

0.308 mOsmol/mL (calc)

NEXUS
PHARMACEUTICALS



SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14789-133
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14789-133-05	25 in 1 CARTON	10/31/2023	01/31/2026
1	NDC:14789-133-07	10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217535	10/31/2023	01/31/2026

SODIUM CHLORIDE

sodium chloride injection, solution

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Active Ingredient/Active Moiety		
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Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:14789-134-05	25 in 1 CARTON	10/31/2023	02/28/2026
1	NDC:14789-134-07	20 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217535	10/31/2023	02/28/2026

Labeler - Nexus Pharmaceuticals LLC (620714787)

Establishment

Name	Address	ID/FEI	Business Operations
Nexus Pharmaceuticals LLC		620714787	analysis(14789-133, 14789-134)