

AMPHENOL-40- sodium chloride injection, solution
IT3 Medical LLC

Amphenol-40

0.9% Sodium Chloride

Injection, USP

Carpject™ with Luer Lock

Fliptop Plastic Vial

LifeShield™ Fliptop Plastic Vial

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.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

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 litres (1.0 to 1.5 litres 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 Category C. 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	Each
NDC 0409-1918-32 Tub of 50 NDC	NDC 0409-1918-42 2 mL Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System
NDC 0409-1918-33 Tub of 25 NDC	NDC 0409-1918-43 3 mL Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System
NDC 0409-1918-35 Tub of 25 NDC	NDC 0409-1918-45 5 mL Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System
NDC 0409-4888-10 Tray of 25 NDC	NDC 0409-4888-02 10 mL Single-dose Plastic Fliptop Vial
NDC 0409-4888-20 Tray of 25 NDC	NDC 0409-4888-03 20 mL Single-dose Plastic Fliptop Vial
NDC 0409-4888-50 Tray of 25 NDC	NDC 0409-4888-06 50 mL Single-dose Plastic Fliptop Vial
NDC 0409-4888-12 Tray of 25	NDC 0409-4888-01 10 mL Single-dose LifeShield™ Plastic Fliptop Vial

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

Instructions for Use of the Syringe Systems

Instructions for using the Carpuject Syringe are available with the reusable Carpuject Holder, List 2049-02.

Revised:9/2015

Manufactured by: Hospira, Inc., Lake Forest, IL 60045 USA

Assembled and Distributed by IT3 Medical, LLC

For questions or comments: info@IT3-Medical.com, www.IT3-Medical.com

Packaging

NDC 70529-136-02



Amphenol-40

40mg Injectable Tissue Graft

Contents:

- 1 - 40mg Tissue Graft
- 1 - 0.9% Sodium Chloride Injection, USP (10mL)
- 2 - 18-25 Gauge Needles Luer-Lok
- 2 - 5mL Syringe w/ Luer-Lok Tip
- 2 - Alcohol Swabs



BIOLOGICAL

This product contains a sterilized biological device.
Do Not Re-sterilize.
MRI-Compatible.



Single use only



Caution, consult accompanying documents



Consult instructions for use



Temperature limitations

Storage: Store in a cool dry place at 25°C (77°F). Excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.



Lot and Expiration



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AMPHENOL-40

sodium chloride injection, solution

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:70529-136

INTRAVENOUS, INTRAMUSCULAR

Route of AdministrationINTRAVENOUS, INTRAMUSCULAR,
SUBCUTANEOUS**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70529-136-02	1 in 1 PACKAGE	03/01/2017	
1		10 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
NDA authorized generic	NDA018803	03/01/2017	

Labeler - IT3 Medical LLC (079971231)

Revised: 1/2020

IT3 Medical LLC