

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

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**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<sup>+</sup>) and chloride (Cl<sup>-</sup>) 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<sup>+</sup>) and chloride (Cl<sup>-</sup>) 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<sup>+</sup>) 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   |
|---|--|
| <b>NDC 0409-1918-32</b><br>Tub of 50 NDC  | NDC 0409-1918-42<br>2 mL Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System |
| <b>NDC 0409-1918-33</b><br>Tub of 25 NDC  | NDC 0409-1918-43<br>3 mL Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System |
| <b>NDC 0409-1918-35</b><br>Tub of 25 NDC  | NDC 0409-1918-45<br>5 mL Carpuject™, Single-dose cartridge with Luer Lock for the Carpuject Syringe System |
| <b>NDC 0409-4888-10</b><br>Tray of 25 NDC | NDC 0409-4888-02<br>10 mL Single-dose Plastic Fliptop Vial   |
| <b>NDC 0409-4888-20</b><br>Tray of 25 NDC | NDC 0409-4888-03<br>20 mL Single-dose Plastic Fliptop Vial   |
| <b>NDC 0409-4888-50</b><br>Tray of 25 NDC | NDC 0409-4888-06<br>50 mL Single-dose Plastic Fliptop Vial   |
| <b>NDC 0409-4888-12</b>                   | NDC 0409-4888-01   |

4000-12  
Tray of 25

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](mailto:info@IT3-Medical.com), [www.IT3-Medical.com](http://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.



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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

**Route of Administration**INTRAVENOUS, INTRAMUSCULAR,  
SUBCUTANEOUS**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| Ingredient Name                             | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)             |          |
| <b>HYDROCHLORIC ACID</b> (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: 2/2022

IT3 Medical LLC