Medefil, Inc. Sodium Chloride Injection, USP, O.9%

Medefil, Inc. is the first manufacturer in the U.S. of Sodium Chloride Injection, USP, O.9% in a pre-filled syringe for human use [New Drug Application (NDA) 202832]. Medefil a manufacturer of pre-filled syringes since 2000 is committed to provide highest quality of products.

Indication of Use of Medefil’s Sodium Chloride Injection, USP, O.9% Syringe:

- For diluting or dissolving of drugs for intravenous, intramuscular or subcutaneous injection, and
- Can also be used for flushing of compatible intravenous tubing and/or indwelling access device (IVAD)

This product is an alternate to vials, small and large volume parenteral bags for diluting/dissolving the drugs

Medefil’s Sodium Chloride Injection, USP, O.9% characteristics are:

- Sterile
- Nonpyrogenic
- An isotonic solution
- Formulated with Sodium Chloride, USP in Water for Injection, USP
- Terminally sterilized using steam
- Contains no preservatives
- Contains no components of natural rubber latex
- Label and tip cap color coded
- Single use syringe available in various fill volumes
- Convenient to use pre-filled syringe

Medefil Uses an Automated, State-of-the-Art Manufacturing Process:

Medefil’s manufacturing process adheres to the parental drug manufacturing industry quality standards for product safety and efficacy. Our automated vision inspection system monitors particulate matters in the solution ensuring that each syringe is diligently inspected.

Learn More about Medefil’s Sodium Chloride Injection, USP, O.9%:

Please call (630) 682-4600 or via e-mail at: info@medefilinc.com
Visit the company’s website at www.medefilinc.com
**Products & Packaging:**

**Sodium Chloride Injection, USP, O.9% Syringe**

<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Description</th>
<th>NDC Number</th>
<th>Box/Case Quantity</th>
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<tbody>
<tr>
<td>MSD-0221</td>
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<td>60/Box, 960/Case</td>
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**Important Safety Information:**

**WARNINGS AND PRECAUTIONS**

General - When used to dilute drug products, consult the drug product manufacturer’s instructions for choice of vehicle, appropriate dilution or volume for dissolving 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. Do not use Sodium Chloride USP 0.9% if the solution is discolored, cloudy, hazy, or contains a precipitate, or if the syringe is damaged.

*For Single Use Only* - Re-use of single-use product creates a potential risk to the user. Contamination of product and/or limited functionality of the device may lead to injury, illness or death. Discard any unused portion.

**ADVERSE REACTIONS** - Adverse reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include, but are not limited to, air embolization, 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 therapeutic countermeasures, and if possible, retrieve and save the remainder of unused vehicle for examination if deemed necessary.

**DRUG INTERACTIONS** - Some drugs or injections may be incompatible when combined with 0.9% sodium chloride. Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, the drug product manufacturer’s instructions or other specific references should be checked for any possible incompatibility with sodium chloride. Consult with a pharmacist, if unsure of compatibility.

*For complete prescribing information, refer to the package insert.*

Date 10/4/12