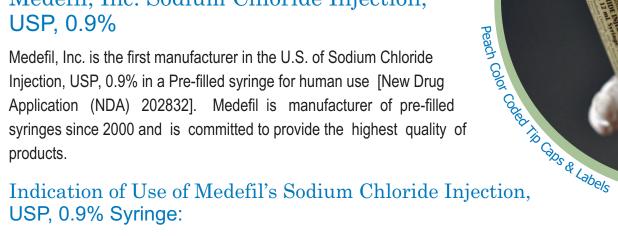


Medefil, Inc. Sodium Chloride Injection, USP, 0.9%

Medefil. Inc. is the first manufacturer in the U.S. of Sodium Chloride Injection, USP, 0.9% in a Pre-filled syringe for human use [New Drug Application (NDA) 202832]. Medefil is manufacturer of pre-filled syringes since 2000 and is committed to provide the highest quality of products.



• For diluting or dissolving the drugs for intravenous, intramuscular or subcutaneous injection.

Medefil, Inc. Sodium Chloride Injection, USP, 0.9% Characteristics are:



Robotic Loading

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

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 diligently inspects for particulate matter ensuring that we produce Quality Products.



Products & Packaging:

Sodium Chloride Injection, USP, 0.9% Syringe

Medefil Catalog #	NDC Number	Description		Box/Case Quantity
MSD-0230	64253-0202-30	10mL Fill in 12mL	_ Syringe	60/Box, 960/Case

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 Injection, 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 specie 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.



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