

Launching SWFI - first in the USA in plastic pre-filled syringe

# Sterile Water for Injection, USP



## Benefits and Features

- Drug Shortage product\*
- Ready-to-use prefilled syringe for diluting or dissolving drugs
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- No Preservatives
- Reduce injectable compounding steps
- Not made with natural rubber latex, DEHP, or PVC
- AP rated
- Bar Coded

Product #	NDC	Description	Fill Volume	Concentration	Unit of Sale	Bar Coded
02030	64253-0020-30	Pre-filled Syringe	10 mL	100%	60	✓

## Wholesaler Item Number

AmerisourceBergen	Cardinal Health	Morris & Dickson	McKesson MedSurg
10237367	5659065	905752	1172488

To learn more about Medefil's Sterile Water for Injection USP  
please visit our website at [www.medefilinc.com](http://www.medefilinc.com), call (630) 682-4600,  
or via email at: [info@medefilinc.com](mailto:info@medefilinc.com)

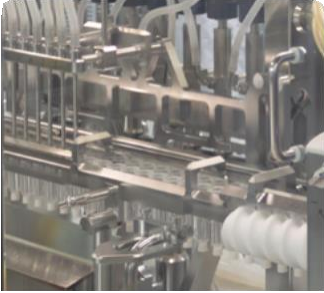
\*On ASHP drug shortage list

# LAUNCHING STERILE WATER FOR INJECTION, USP

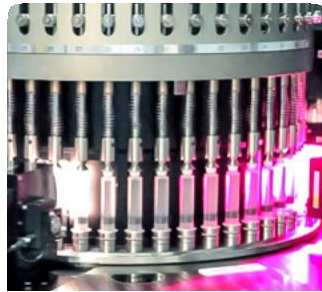
## About Medefil

Medefil is growing as a fully integrated specialty pharmaceutical company. At Medefil our goal is to develop and manufacture injectable products where quality and supply reliability are crucial, and safety and ease-of use are of utmost importance. Medefil has a state-of-the-art scientific research infrastructure and high-quality manufacturing capabilities leading to effective execution of development and product supply.

## State-of-the-art Manufacturing



Filling



Inspection



Labeling



Packaging

## Important Safety Information

### Warnings:

Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.

### Precautions:

Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture.

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 Sterile Water for Injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection with additives should be given to a pregnant woman only if clearly needed.

### 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.

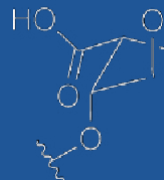
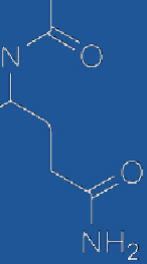
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

### Overdosage:

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of 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 **WARNINGS**, **PRECAUTIONS** and **ADVERSE REACTIONS**.

To report SUSPECTED ADVERSE REACTIONS, contact Medefil, Inc. at 1-630-682-4600 or [www.medefilinc.com](http://www.medefilinc.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

For complete prescribing information, refer to the package insert.



# 10% Calcium Chloride Injection, USP



## Benefits and Features

- Drug shortage product\*
- Ready-to-administer prefilled syringe
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- No preservatives
- Not made with natural rubber latex, DEHP, or PVC
- AP rated
- Bar coded

NDC	Description	Strength	Fill Volume	Concentration	Unit of Sale	Bar Coded
64253-0900-36	Syringe	1000 mg/ 10mL	10 mL	100 mg/mL	60	✓

## Wholesaler Item Number

AmerisourceBergen	Cardinal Health	Morris & Dickson	McKesson MedSurg
10229819	5566435	781773	1158369

To learn more about Medefil's 10% Calcium Chloride Injection USP please visit our website at [www.medefilinc.com](http://www.medefilinc.com), call (630) 682-4600, or via email at: [info@medefilinc.com](mailto:info@medefilinc.com)

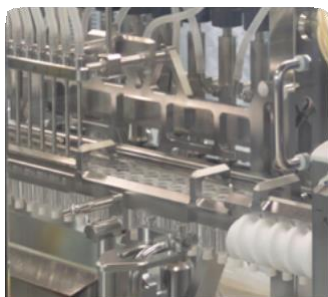
\*On FDA and ASHP drug shortage list

# 10% Calcium Chloride Injection, USP

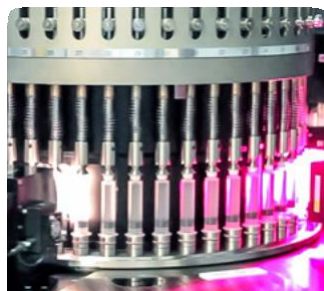
## About Medefil

Medefil is growing as a fully integrated specialty pharmaceutical company. At Medefil our goal is to develop and manufacture injectable products where quality and supply reliability are crucial, and safety and ease-of use are of utmost importance. Medefil has a state-of-the-art scientific research infrastructure and high-quality manufacturing capabilities leading to effective execution of development and product supply.

## State-of-the-art Manufacturing



Filling



Inspection



Labeling



Packaging

## Important Safety Information

### Warnings:

10% Calcium Chloride Injection, USP is irritating to veins and **must not be injected into tissues**, since severe necrosis and sloughing may occur. Great care should be taken to avoid extravasation or accidental injection into perivascular tissues.

**Warning:** This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

### Precautions:

Do not administer solution if clear and seal is intact. Discard unused portion.

Because of its additive effect, calcium should be administered very cautiously to a patient who is digitalized or who is taking effective doses of digitalis or digitalis-like preparations.

Injections should be made slowly through a small needle into a large vein to minimize venous irritation and avoid undesirable reactions.

It is particularly important to prevent a high concentration of calcium from reaching the heart because of the danger of cardiac syncope.

### For Single Use Only:

Reuse of single-use products contains a potential risk to the user. Contamination of the product and/or limited functionality of the device may lead to injury, illness or death. Discard unused portion.

### Adverse Reactions:

Rapid injection may cause the patient to complain of tingling sensations, a calcium taste, a sense of oppression or "heat wave".

Injections of calcium chloride are accompanied by peripheral vasodilatation as well as a local "burning" sensation and there may be a moderate fall in blood pressure.

Should perivascular infiltration occur, I.V. administration at that site should be discontinued at once. Local infiltration of the affected area with 1% procaine hydrochloride, to which hyaluronidase may be added, will often reduce venospasm and dilute the calcium remaining in the tissues locally. Local application of heat may also be helpful.

To report SUSPECTED ADVERSE REACTIONS, contact Medefil, Inc. at 1-630-682-4600 or [www.medefilinc.com](http://www.medefilinc.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

For complete prescribing information, refer to the package insert.



Medefil Inc.

[www.medefilinc.com](http://www.medefilinc.com)





# MEDEFIL, INC.

## 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.

### Indication of Use of Medefil's Sodium Chloride Injection, USP, 0.9% Syringe:

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



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



Learn More about Medefil's Sodium Chloride Injection, USP, 0.9%:  
Please call (630) 682-4600 or via e-mail at: [info@medefilinc.com](mailto:info@medefilinc.com)  
Visit the company's website at [www.medefilinc.com](http://www.medefilinc.com)



## 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 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.



### MEDEFIL, INC.

250 Windy Point Drive  
Glendale Heights Illinois 60139  
Phone (630) 682-4600  
Fax (630) 681-9100  
[www.medefilinc.com](http://www.medefilinc.com)

MED-12-002, Rev. 002.

Learn More about Medefil's Sodium Chloride Injection, USP, 0.9%:  
Please call (630) 682-4600 or via e-mail at: [info@medefilinc.com](mailto:info@medefilinc.com)  
Visit the company's website at [www.medefilinc.com](http://www.medefilinc.com)



# MEDEFIL, INC.

Why Should I Choose **MedeFlush™**?

No Reflux Post Flushing = Lower Catheter Occlusion

ISO Compliant Syringe = Helping your Institution Stay Compliant

Pharmaceutical Grade Syringe = Syringe Designed for the Pre-Filled Application

Quality Plastics = No Barrel Distortion = Helps in Maintaining Solution & its Pathway Sterile

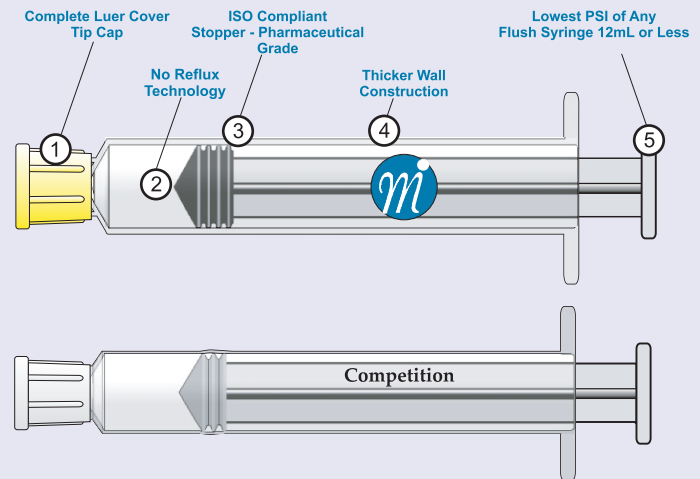
Plunger Stopper with Four Rings = ISO Requirements for a Pre-Filled Syringe

Terminally Sterilized Product = Contributes to Patient Safety

Great Pricing

## MedeFlush™ Features:

- Contains No Preservatives, Not made with Natural Rubber Latex & DEHP
- Color-Coded Tip Caps and Labels for easier Identification and/or helps Decreased Medication Errors
- Clear Plastic Syringes for Better Visibility of Syringe Contents
- 6mL & 12mL Syringes with Same Large Diameter
- State-of-the-Art Fully Automated Facility
- Minimal Human Interface during Manufacturing Process
- State-of-the-Art Injectables Solution Formulation Plant
- Bar Code, NDC & Catalog Number on Each Syringe
- Two Year Expiry Dating
- Lot Number & Expiration Date on Each Syringe
- Terminally Sterilized with Steam (SAL  $10^{-6}$ )
- Compatible with Needleless and I. V. Access Systems



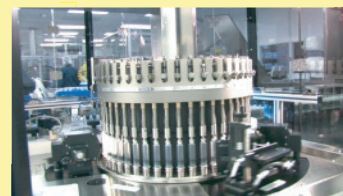
## State-of-the-Art Manufacturing



Filling



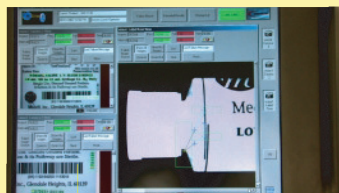
Terminal Sterilization



Inspection



Labeling



Graduation and Label QC



Packaging

MedeFlush™ larger barrel diameter creates a smooth flow of flush solution with less pressure per square inch.

Good for reduced flow catheters. All this with NO REFLUX technology.

MedeFlush™ pre-filled syringes are manufactured in accordance with the applicable provisions of 21 Code of Federal Regulations (CFR) including Current Good Manufacturing Practices (cGMP) and Quality Control Requirements.

Learn more about Medefil's **MedeFlush™** Products

Please call (630) 682-4600 or via e-mail at: [info@medefilinc.com](mailto:info@medefilinc.com)

Visit the company's website at [www.medefilinc.com](http://www.medefilinc.com)



## Products and Packaging

### Normal Saline I. V. Flush Syringes [0.9% Sodium Chloride Injection] 510(k) K091583

Catalog #	NDC Number	Description	Box / Case Quantity
MIS-1123	64253-0111-23	3mL fill in 6mL Syringe	60/Box, 960/case
MIS-1125	64253-0111-25	5mL fill in 6mL Syringe	60/Box, 960/case
MIS-1133	64253-0111-33	3mL fill in 12mL Syringe	60/Box, 960/case
MIS-1135	64253-0111-35	5mL fill in 12mL Syringe	60/Box, 960/case
MIS-1130	64253-0111-30	10mL fill in 12mL Syringe	60/Box, 960/case

### 1 USP Unit/mL Heparin I. V. Flush Syringes 510(k) K092491

Catalog #	NDC Number	Description	Box / Case Quantity
MIH-4422	64253-0444-22	2mL fill in 6mL Syringe	60/Box, 960/case
MIH-4425	64253-0444-25	5mL fill in 6mL Syringe	60/Box, 960/case

Heparin I.V. Flush Syringes in 0.9% Sodium Chloride

### 10 USP Units/mL Heparin I. V. Flush Syringes 510(k) K092491

Catalog #	NDC Number	Description	Box / Case Quantity
MIH-2221	64253-0222-21	1mL fill in 6mL Syringe	60/Box, 960/case
MIH-2223	64253-0222-23	3mL fill in 6mL Syringe	60/Box, 960/case
MIH-2233	64253-0222-33	3mL fill in 12mL Syringe	60/Box, 960/case
MIH-2235	64253-0222-35	5mL fill in 12mL Syringe	60/Box, 960/case

Heparin I.V. Flush Syringes in 0.9% Sodium Chloride

### 100 USP Units/mL Heparin I. V. Flush Syringes 510(k) K092491

Catalog #	NDC Number	Description	Box / Case Quantity
MIH-3321	64253-0333-21	1mL fill in 6mL Syringe	60/Box, 960/case
MIH-3323	64253-0333-23	3mL fill in 6mL Syringe	60/Box, 960/case
MIH-3333	64253-0333-33	3mL fill in 12mL Syringe	60/Box, 960/case
MIH-3335	64253-0333-35	5mL fill in 12mL Syringe	60/Box, 960/case

Heparin I.V. Flush Syringes in 0.9% Sodium Chloride



#### MEDEFIL, INC.

250 Windy Point Drive  
Glendale Heights Illinois 60139  
Phone (630) 682-4600  
Fax (630) 681-9100  
www.medefilinc.com

MED-12-001, Rev. 001

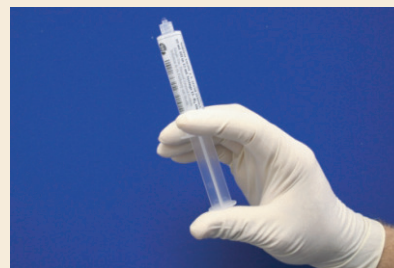
## Instructions for Use



Open using the perforation on the package.



With the tip cap of the syringe on, press the syringe forward to activate syringe.



Remove tip cap and prime the syringe luer.



Per Institution protocol, attach flush syringe to access device and flush.



Dispose of used syringe in an appropriate container.

Learn more about Medefil's **MedeFlush™** Products

Please call (630) 682-4600 or via e-mail at: [info@medefilinc.com](mailto:info@medefilinc.com)

Visit the company's website at [www.medefilinc.com](http://www.medefilinc.com)