Newly Launched Product

Atropine Sulfate Injection, USP

Benefits and Features

- Not made with natural rubber latex, DEHP, or PVC
- No Preservatives
- AP rated
- Luer Lock syringe compatible with Luer-Activated IV Systems
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- Bar Coded

Product Information

UoS† NDC	Product #	Fill Volume	Concentration (mg/mL)	Content	Unit / BX	Bar Coded
64253-0400-91	40091	10 mL	0.1 mg/mL	1 mg/10 mL	10	√

Wholesalers Item Number

AmerisourceBergen	Cardinal Health	McKesson Drug	McKesson MedSurg	Morris & Dickson
10278983	5839824	2696144	1231706	274100

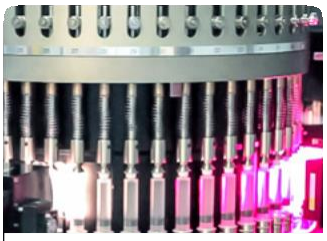
To learn more about Medefil's Atropine Sulfate Injection, USP please visit our website at www.medefilinc.com, call (630) 682-4600, or via email at: info@medefilinc.com

Atropine Sulfate 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



Inspection

Labeling

Packaging

Important Safety Information

WARNINGS AND PRECAUTIONS:

Tachycardia: When the recurrent use of atropine is essential in patients with coronary artery disease, the total dose should be restricted to 2 to 3 mg (maximum 0.03 to 0.04 mg/kg) to avoid the detrimental effects of atropine-induced tachycardia on myocardial oxygen demand.

Acute Glaucoma: Atropine may precipitate acute glaucoma.

Pyloric Obstruction: Atropine may convert partial organic pyloric stenosis into complete obstruction.

Complete Urinary Retention: Atropine may lead to complete urinary retention in patients with prostatic hypertrophy.

Viscid Plugs: Atropine may cause inspissation of bronchial secretions and formation of viscid plugs in patients with chronic lung disease.

DRUG INTERACTIONS:

Atropine Sulfate Injection decreased the rate of mexiletine absorption without altering the relative oral bioavailability; this delay in mexiletine absorption was reversed by the combination of atropine and intravenous metoclopramide during pretreatment for anesthesia.

ADVERSE REACTIONS:

Most of the side effects of atropine are directly related to its antimuscarinic action. Dryness of the mouth, blurred vision, photophobia and tachycardia commonly occur. Anhidrosis can produce heat intolerance. Constipation and difficulty in micturition may occur in elderly patients. Occasional hypersensitivity reactions have been observed, especially skin rashes which in some instances progressed to exfoliation.

OVERDOSAGE:

Excessive dosing may cause palpitation, dilated pupils, difficulty in swallowing, hot dry skin, thirst, dizziness, restlessness, tremor, fatigue and ataxia. Toxic doses lead to restlessness and excitement, hallucinations, delirium and coma. Depression and circulatory collapse occur only with severe intoxication. In such cases, blood pressure declines and death due to respiratory failure may ensue following paralysis and coma.

The fatal adult dose of atropine is not known. In pediatric populations, 10 mg or less may be fatal.

In the event of toxic overdosage, a short acting barbiturate or diazepam may be given as needed to control marked excitement and convulsions. Large doses for sedation should be avoided because central depressant action may coincide with the depression occurring late in atropine poisoning. Central stimulants are not recommended.

Physostigmine, given as an atropine antidote by slow intravenous injection of 1 to 4 mg (0.5 to 1 mg in pediatric populations), rapidly abolishes delirium and coma caused by large doses of atropine. Since physostigmine is rapidly destroyed, the patient may again lapse into coma after one to two hours, and repeated doses may be required.

Artificial respiration with oxygen may be necessary. Ice bags and alcohol sponges help to reduce fever, especially in pediatric populations.

Atropine is not removed by dialysis.

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

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) 682-9100 | www.medefilinc.com

MED-12-006; Rev. 000

First in the USA in plastic pre-filled syringe

Sterile Water for Injection, USP

Benefits and Features

- Ready-to-use prefilled syringe for diluting or dissolving drugs
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- Not made with natural rubber latex, DEHP, or PVC
- Luer Lock syringe compatible with Luer-Activated IV Systems
- Reduce injectable compounding steps
- AP rated
- Bar Coded
- No Preservatives

SKU(s) in Product Family

UoS† NDC	Product #	Fill Volume	Unit / BX	Bar Coded
64253-0020-30	MIW-2030	10 mL	60	√
64253-0020-91	02091	10mL	10	√

Wholesalers Item Number

UoS† NDC	AmerisourceBergen	Cardinal Health	McKesson Drug	McKesson MedSurg	Morris & Dickson
64253-0020-30	10237367	5659065	2315257	1172488	905752
64253-0020-91	10257591	5716808	1569102	1179480	021204

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

Sterile Water for Injection, USP

About Medefil

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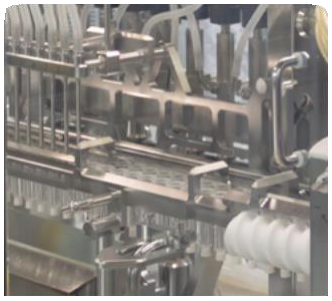
State-of-the-art Manufacturing



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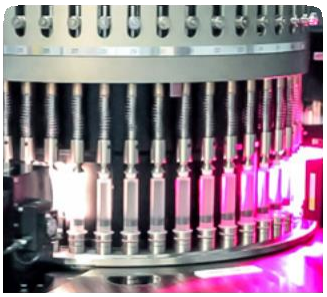

Inspection

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 or FDA at
1-800-FDA-1088 or www.fda.gov/medwatch.

For complete prescribing information, refer to the package insert.

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Phone (630) 682-4600 | Fax (630) 682-9100 | www.medefilinc.com

MED-12-005; Rev 002.

10% Calcium Chloride Injection, USP

Benefits and Features

- Ready-to-administer prefilled syringe
- Not made with natural rubber latex, DEHP, or PVC
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- Luer Lock syringe compatible with Luer-Activated IV Systems
- AP rated
- Bar Coded
- No preservatives

SKU(s) in Product Family

UoS† NDC	Product #	Fill Volume	Concentration (mg/mL)	Content	Unit / BX	Bar Coded
64253-0900-36	MCC-0030	10 mL	100 mg/mL	1000 mg/10 mL	60	✓
64253-0900-91	90091	10 mL	100 mg/mL	1000 mg/10 mL	10	✓

Wholesalers Item Number

UoS† NDC	AmerisourceBergen	Cardinal Health	McKesson Drug	McKesson MedSurg	Morris & Dickson
64253-0900-36	10229819	5566435	2315224	1158369	781773
64253-0900-91	10257314	5716816	1569037	1179481	021196

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

10% Calcium Chloride Injection, USP

About Medefil

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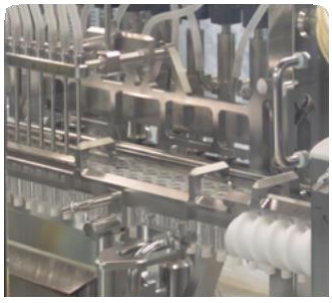
State-of-the-art Manufacturing



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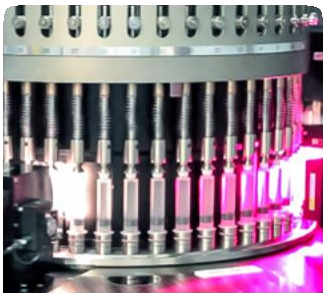

Inspection

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 is 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 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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MED-12-004; Rev. 002

MEDEFIL, INC.

Peach Color Coded Tip Caps & Labels

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:


Robotic Loading System

- ✔ 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
Visit the company's website at www.medefilinc.com

MEDEFIL, INC.

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 specic 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
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Fax (630) 681-9100
www.medefilinc.com

MED-12-002, Rev. 002. 07/2016

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

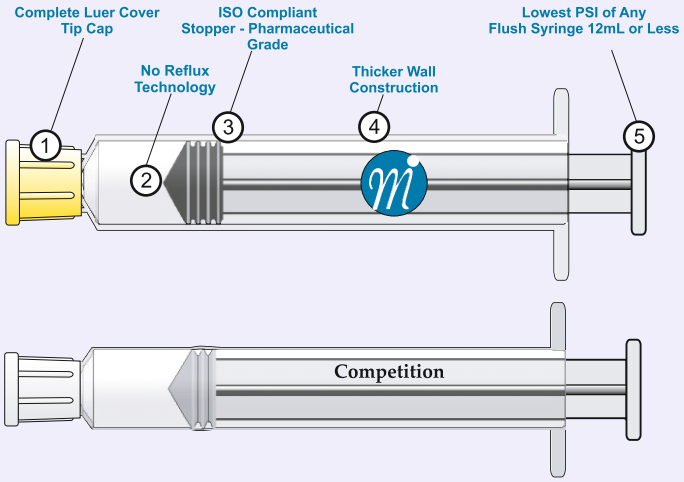
MEDEFIL, INC.

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
- 6 mL & 12 mL 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, UDI & 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



- 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.

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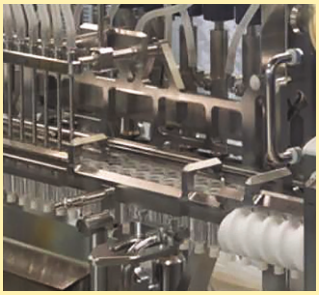
State-of-the-Art Manufacturing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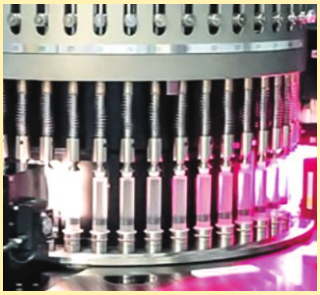
Inspection


Labeling


Packaging

Learn more about Medefil's **MedeFlush™** Products
Please call (630) 682-4600 or via e-mail at: info@medefilinc.com
Visit the company's website at www.medefilinc.com

MedeFlush™

ISO 13485: 2016 Certified
ISO 9001: 2015 Certified

Normal Saline I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIS-1123	3mL fill in 6mL Syringe	64253-111-23	60/Box, 960/case
MIS-1125	5mL fill in 6mL Syringe	64253-111-25	60/Box, 960/case
MIS-1133	3mL fill in 12mL Syringe	64253-111-33	60/Box, 960/case
MIS-1135	5mL fill in 12mL Syringe	64253-111-35	60/Box, 960/case
MIS-1130	10mL fill in 12mL Syringe	64253-111-30	60/Box, 960/case

1 Unit/mL Heparin I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIH-4422	2mL fill in 6mL Syringe	64253-444-22	60/Box, 960/case
MIH-4425	5mL fill in 6mL Syringe	64253-444-25	60/Box, 960/case

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

10 Units/mL Heparin I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIH-2221	1mL fill in 6mL Syringe	64253-222-21	60/Box, 960/case
MIH-2223	3mL fill in 6mL Syringe	64253-222-23	60/Box, 960/case
MIH-2233	3mL fill in 12mL Syringe	64253-222-33	60/Box, 960/case
MIH-2235	5mL fill in 12mL Syringe	64253-222-35	60/Box, 960/case

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

100 Units/mL Heparin I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIH-3321	1mL fill in 6mL Syringe	64253-333-21	60/Box, 960/case
MIH-3323	3mL fill in 6mL Syringe	64253-333-23	60/Box, 960/case
MIH-3333	3mL fill in 12mL Syringe	64253-333-33	60/Box, 960/case
MIH-3335	5mL fill in 12mL Syringe	64253-333-35	60/Box, 960/case

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

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Phone (630) 682-4600 | Fax (630) 681-9100 | www.medefilinc.com

MedeFlush™

Prefilled Heparin Syringes (1 Unit/mL) for Neonatal Intensive Care Units

- Low-dose prefilled heparin syringes designed specifically for use in Neonatal Intensive Care Units (NICU)
- Tip cap and label are color-coded by concentration to prevent medication errors
- Two year shelf life, compared to pharmacy-compounded alternatives (typical shelf life of seven days)
- No Reflux Technology
- Lowest PSI of any Flush Syringe (12mL or less) creates smooth flow of flush solution with less pressure.
- Thicker wall construction eliminates barrel distortion, keeping fluid in the sterile zone of the syringe.
- Preservative free, DEHP free, Latex free
- Bar code & UDI on each Syringe

Learn more about medifil's MedeFlush Products
Please call (630) 682-4600 or via e-mail at: info@medefilinc.com
Visit the company's website at www.medefilinc.com

MedeFlush™

ISO 13485: 2016 Certified
ISO 9001: 2015 Certified

Normal Saline I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIS-1123	3mL fill in 6mL Syringe	64253-111-23	60/Box, 960/case
MIS-1125	5mL fill in 6mL Syringe	64253-111-25	60/Box, 960/case
MIS-1133	3mL fill in 12mL Syringe	64253-111-33	60/Box, 960/case
MIS-1135	5mL fill in 12mL Syringe	64253-111-35	60/Box, 960/case
MIS-1130	10mL fill in 12mL Syringe	64253-111-30	60/Box, 960/case

1 Unit/mL Heparin I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIH-4422	2mL fill in 6mL Syringe	64253-444-22	60/Box, 960/case
MIH-4425	5mL fill in 6mL Syringe	64253-444-25	60/Box, 960/case

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

10 Units/mL Heparin I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIH-2221	1mL fill in 6mL Syringe	64253-222-21	60/Box, 960/case
MIH-2223	3mL fill in 6mL Syringe	64253-222-23	60/Box, 960/case
MIH-2233	3mL fill in 12mL Syringe	64253-222-33	60/Box, 960/case
MIH-2235	5mL fill in 12mL Syringe	64253-222-35	60/Box, 960/case

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

100 Units/mL Heparin I.V. Flush Syringes

Catalog #	Description	UDI	Box / Case Quantity
MIH-3321	1mL fill in 6mL Syringe	64253-333-21	60/Box, 960/case
MIH-3323	3mL fill in 6mL Syringe	64253-333-23	60/Box, 960/case
MIH-3333	3mL fill in 12mL Syringe	64253-333-33	60/Box, 960/case
MIH-3335	5mL fill in 12mL Syringe	64253-333-35	60/Box, 960/case

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

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