

STERILE WATER- sterile water for injection injection, solution Medefil, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use STERILE WATER FOR INJECTION, USP safely and effectively. See full prescribing information for STERILE WATER FOR INJECTION, USP.

STERILE WATER FOR INJECTION, USP for Intravenous, Intramuscular, and Subcutaneous Injection

Initial U.S. Approval: 2019

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.

(3)

CONTRAINDICATIONS

Sterile Water for Injection, USP must be made approximately isotonic prior to use. (4)

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. (6.3)

(6.3)

(6.3)

When diluting or dissolving drugs, mix thoroughly and use promptly. (6.3)

(6.3)

(6.3)

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute. (6.3)

(6.3)

(6.3)

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers. Discard unused portion. (6.3)

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.

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.

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. (9)

(9)

(9)

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. (9)

Revised: 9/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

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.

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. For intravenous injection, add sufficient solute to make an approximately isotonic solution. pH 5.0 to 7.0.

Water for Injection, USP is chemically designated H₂O.

The plastic syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the syringe material.

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 liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water for distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na⁺) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP when used only as a Pharmaceutical aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in neonates or very small infants.

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.

Sterile Water for Injection, USP must be made approximately isotonic prior to use.

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

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.

Safety and effectiveness have been established in pediatric patients. However, in neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

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.

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.

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.

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.

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**.

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.

Sterile Water for Injection, USP is supplied in the following:

Product	NDC Number
Sterile Water for Injection, USP 1 mL, Single-dose pre-filled syringe, carton of 10s	64523-020-41
Sterile Water for Injection, USP 2.5 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-51
Sterile Water for Injection, USP 3 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-61
Sterile Water for Injection, USP* 5 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-71

Sterile Water for Injection, USP** 5 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-81
Sterile Water for Injection, USP 10 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-91
Sterile Water for Injection, USP 1 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-21
Sterile Water for Injection, USP 2.5 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-52
Sterile Water for Injection, USP 3 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-23
Sterile Water for Injection, USP* 5 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-25
Sterile Water for Injection, USP** 5 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-35
Sterile Water for Injection, USP 10 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-30

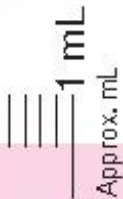
*in 6 mL Syringe **in 12 mL Syringe

Discard unused portion

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]. Protect from freezing

1 mL Single-dose pre-filled syringe NDC 64253-020-21

WARNINGS: NOT ISOTONIC, HEMOLYTIC



Rx only

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic.

Contains no antimicrobial or other added substance

Discard unused portion. Sterile, nonpyrogenic. pH 5.0 to 7.0

Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F).

Protect from freezing.



(01) 10364253020213



Medefil, Inc., Glendale Heights, IL 60139

Rev. 001 (03/2020)

LOT/EXP. 

L4294

NDC 64253-020-21

60 X 1 mL Single-Dose Pre-filled Syringes

WARNINGS: NOT ISOTONIC, HEMOLYTIC

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic

Contains no antimicrobial or other added substance

Do not use if solution is discolored, hazy, or contains a precipitate.

Usual dosage: See insert. Discard unused portion.

Sterile, nonpyrogenic. pH 5.0 to 7.0

Recommended Storage: Store at 20 to 25°C (68 to 77°F). [See USP
Controlled Room Temperature.] Protect from freezing. Rx only



NOT MADE
WITH NATURAL
RUBBER LATEX



SINGLE USE



**SOLUTION
AND PATHWAY
ARE STERILE**



NO PRESERVATIVES



Medefil, Inc., Glendale Heights, IL 60139

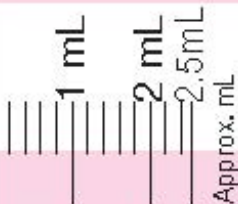


(01)30364253020217

L4299 Rev. 000 (12/2019)

2.5 mL Single-dose pre-filled syringe NDC 64253-020-52

WARNINGS: NOT ISOTONIC, HEMOLYTIC



Rx only

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic.

Contains no antimicrobial or other added substance

Discard unused portion. Sterile, nonpyrogenic. pH 5.0 to 7.0

Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F).

Protect from freezing.



(01) 10364253020527



Medefil, Inc., Glendale Heights, IL 60139

Rev. 001 (03/2020)

LOT/EXP. 

L4296

NDC 64253-020-52

60 X 2.5 mL Single-Dose Pre-filled Syringes

WARNINGS: NOT ISOTONIC, HEMOLYTIC

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic

Contains no antimicrobial or other added substance

Do not use if solution is discolored, hazy, or contains a precipitate.

Usual dosage: See insert. Discard unused portion.

Sterile, nonpyrogenic. pH 5.0 to 7.0

Recommended Storage: Store at 20 to 25°C (68 to 77°F). [See USP
Controlled Room Temperature.] Protect from freezing. Rx only



NOT MADE
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RUBBER LATEX



SINGLE USE



**SOLUTION
AND PATHWAY
ARE STERILE**



NO PRESERVATIVES



Medefil, Inc., Glendale Heights, IL 60139

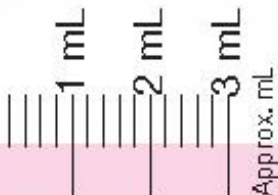


(01)30364253020521

L4300 Rev. 000 (12/2019)

3 mL Single-dose pre-filled syringe NDC 64253-020-23

WARNINGS: NOT ISOTONIC, HEMOLYTIC



Rx only

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic.

Contains no antimicrobial or other added substance

Discard unused portion. Sterile, nonpyrogenic. pH 5.0 to 7.0

Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F).

Protect from freezing.



(01) 10364253020237



Medefil, Inc., Glendale Heights, IL 60139

Rev. 001 (03/2020)

LOT/EXP.

L4295

NDC 64253-020-23

60 X 3 mL Single-Dose Pre-filled Syringes

WARNINGS: NOT ISOTONIC, HEMOLYTIC

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic

Contains no antimicrobial or other added substance

Do not use if solution is discolored, hazy, or contains a precipitate.

Usual dosage: See insert. Discard unused portion.

Sterile, nonpyrogenic. pH 5.0 to 7.0

Recommended Storage: Store at 20 to 25°C (68 to 77°F). [See USP
Controlled Room Temperature.] Protect from freezing. Rx only



NOT MADE
WITH NATURAL
RUBBER LATEX



SINGLE USE



**SOLUTION
AND PATHWAY
ARE STERILE**



NO PRESERVATIVES



Medefil, Inc., Glendale Heights, IL 60139

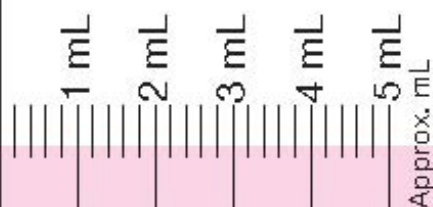


(01)30364253020231

L4301 Rev. 000 (12/2019)

5 mL Single-dose pre-filled syringe NDC 64253-020-35

WARNINGS: NOT ISOTONIC, HEMOLYTIC



Rx only

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic.

Contains no antimicrobial or other added substance

Discard unused portion. Sterile, nonpyrogenic. pH 5.0 to 7.0

Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F).

Protect from freezing.



(01) 10364253020350

Medefil, Inc., Glendale Heights, IL 60139

Rev. 001 (03/2020)

LOT/EXP.

L4297

NDC 64253-020-35

60 X 5 mL Single-Dose Pre-filled Syringes

WARNINGS: NOT ISOTONIC, HEMOLYTIC

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic

Contains no antimicrobial or other added substance

Do not use if solution is discolored, hazy, or contains a precipitate.

Usual dosage: See insert. Discard unused portion.

Sterile, nonpyrogenic. pH 5.0 to 7.0

Recommended Storage: Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. Rx only



NOT MADE
WITH NATURAL
RUBBER LATEX



SINGLE USE



**SOLUTION
AND PATHWAY
ARE STERILE**



NO PRESERVATIVES



Medefil, Inc., Glendale Heights, IL 60139

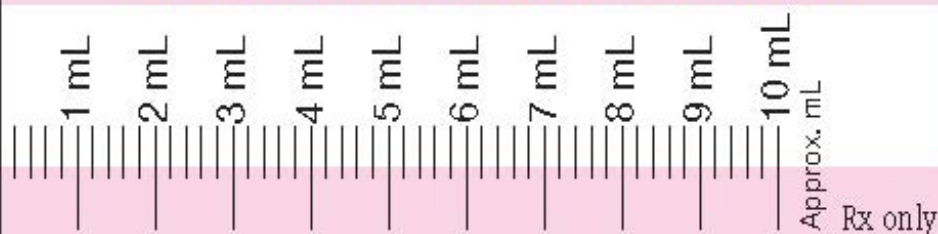


(01)30364253020354

L4302 Rev. 000 (12/2019)

10 mL Single-dose pre-filled syringe NDC 64253-020-30

WARNINGS: NOT ISOTONIC, HEMOLYTIC



**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic.

Contains no antimicrobial or other added substance

Discard unused portion. Sterile, nonpyrogenic. pH 5.0 to 7.0

Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F).

Protect from freezing.



(01) 10364253020305

Medefil, Inc., Glendale Heights, IL 60139

Rev. 001 (03/2020)

LOT/EXP.

L4298

NDC 64253-020-30

60 X 10 mL Single-Dose Pre-filled Syringes

WARNINGS: NOT ISOTONIC, HEMOLYTIC

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic

Contains no antimicrobial or other added substance

Do not use if solution is discolored, hazy, or contains a precipitate.

Usual dosage: See insert. Discard unused portion.

Sterile, nonpyrogenic. pH 5.0 to 7.0

Recommended Storage: Store at 20 to 25°C (68 to 77°F). [See USP
Controlled Room Temperature.] Protect from freezing. Rx only



**SOLUTION
AND PATHWAY
ARE STERILE**



Medefil, Inc., Glendale Heights, IL 60139

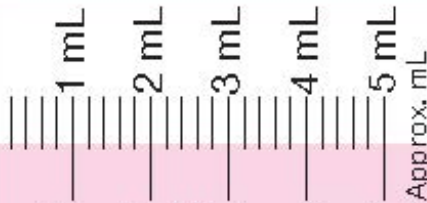


(01)30364253020309

L4303 Rev. 000 (12/2019)

5 mL Single-dose pre-filled syringe NDC 64253-020-25

WARNINGS: NOT ISOTONIC, HEMOLYTIC



Rx only

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic.

Contains no antimicrobial or other added substance

Discard unused portion. Sterile, nonpyrogenic. pH 5.0 to 7.0

Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F).

Protect from freezing.



(01) 1036425302025 1



Medefil, Inc., Glendale Heights, IL 60139

Rev. 000 (03/2020)

LOT/EXP.

L4340

NDC 64253-020-25

60 X 5 mL Single-Dose Pre-filled Syringes

WARNINGS: NOT ISOTONIC, HEMOLYTIC

**Sterile Water for Injection, USP
FOR DRUG DILUENT USE ONLY**

Do not give intravenously unless rendered nearly isotonic

Contains no antimicrobial or other added substance

Do not use if solution is discolored, hazy, or contains a precipitate.

Usual dosage: See insert. Discard unused portion.

Sterile, nonpyrogenic. pH 5.0 to 7.0

Recommended Storage: Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. Rx only



NOT MADE WITH NATURAL RUBBER LATEX



SINGLE USE



SOLUTION AND PATHWAY ARE STERILE



NO PRESERVATIVES

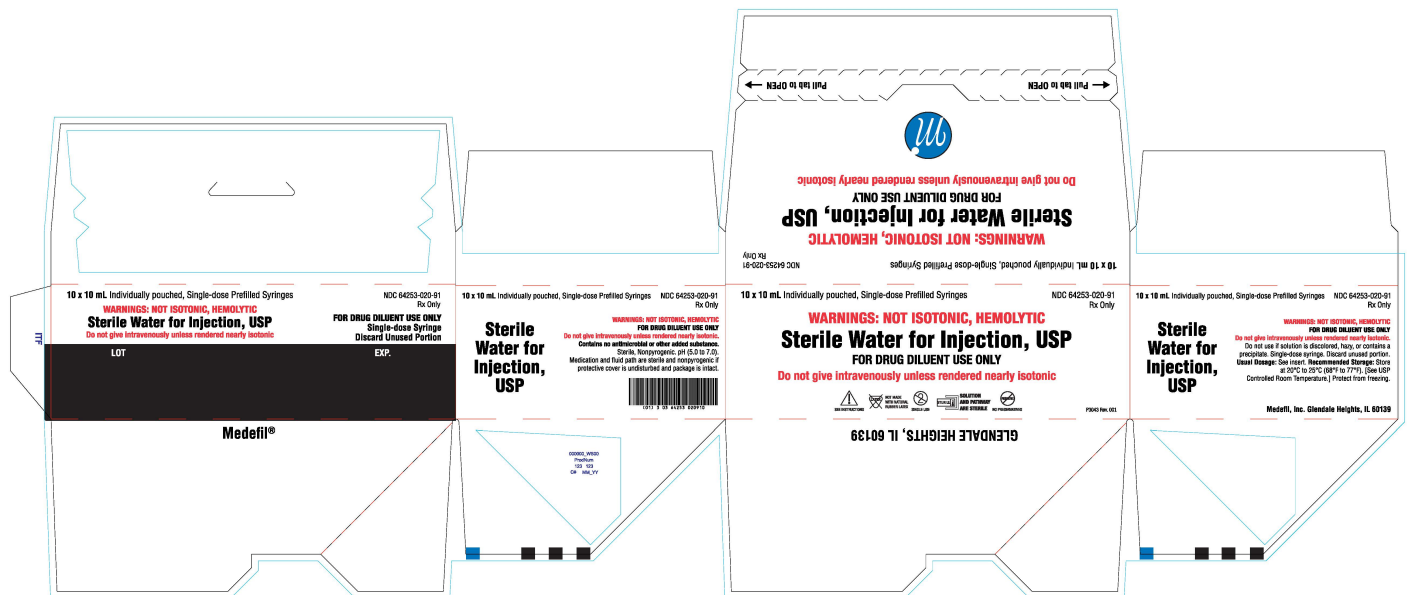


Medefil, Inc., Glendale Heights, IL 60139



(01)30364253020354

L4341 Rev. 000 (06/2020)



Sterile Water for Injection, USP
Plastic Syringe
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.

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. For intravenous injection, add sufficient solute to make an approximately isotonic solution. pH 5.0 to 7.0.

Water for Injection, USP is chemically designated H₂O.

The plastic syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life.

Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the syringe material.

CLINICAL PHARMACOLOGY

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 liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water for distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na⁺) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP when used only as a Pharmaceutical aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in neonates or very small infants.

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.

CONTRAINDICATIONS

Sterile Water for Injection, USP must be made approximately isotonic prior to use.

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.

Pediatric Use

Safety and effectiveness have been established in pediatric patients. However, 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.

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 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.

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

Sterile Water for Injection, USP is supplied in the following:

Product	NDC Number
Sterile Water for Injection, USP 1 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-41
Sterile Water for Injection, USP 2.5 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-51
Sterile Water for Injection, USP 3 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-61
Sterile Water for Injection, USP* 5 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-71
Sterile Water for Injection, USP** 5 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-81
Sterile Water for Injection, USP 10 mL, Single-dose pre-filled syringe, carton of 10s	64253-020-91
Sterile Water for Injection, USP 1 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-21
Sterile Water for Injection, USP 2.5 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-52
Sterile Water for Injection, USP 3 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-23
Sterile Water for Injection, USP* 5 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-25
Sterile Water for Injection, USP** 5 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-35
Sterile Water for Injection, USP 10 mL, Single-dose pre-filled syringe, carton of 60s	64253-020-30

*in 6 mL Syringe **in 12 mL Syringe

Discard unused portion.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.



Medefil, Inc.
Glendale Heights, IL 60139
L4309 Rev. 002 (09/2020)


PEEL OFF

10 mL NDC 64253-020-30
Rx only

**WARNING:
NOT ISOTONIC,
HEMOLYTIC**

**Sterile Water for
Injection, USP**

10 mL Single-dose pre-
filled syringe



Single-dose syringe
**FOR DRUG DILUENT
USE ONLY**


**Do not give intravenously
unless rendered nearly
isotonic**

**Contains no antimicrobial
or other added substance**

Discard unused portion

Sterile, Nonpyrogenic
pH 5.0 to 7.0

Usual dosage: See insert. Store
at 20°C to 25°C (68°F to 77°F);
[See USP Controlled Room
Temperature.]
Protect from freezing


 **Medefil, Inc.**
Glendale Heights, IL 60139


Instructions on back side


P3033 Rev. 003

Use Aseptic Technique

- Remove plastic wrapping by peeling apart.


- Press the plunger rod forward to relieve any resistance that may be present.


- Remove tip cap. Press the plunger rod forward until air is expelled from the syringe.



sterile water for injection injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64253-020
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	100 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64253-020-21	60 in 1 BOX	01/27/2020	
1		1 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:64253-020-23	60 in 1 BOX	01/27/2020	
2		3 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:64253-020-30	60 in 1 BOX	01/27/2020	
3		10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:64253-020-35	60 in 1 BOX	01/27/2020	
4		5 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:64253-020-52	60 in 1 BOX	01/27/2020	
5		2.5 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:64253-020-25	60 in 1 BOX	09/21/2020	
6		5 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
7	NDC:64253-020-91	10 in 1 BOX	09/21/2020	
7		10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211188	01/27/2020	

Labeler - Medefil, Inc. (016448669)

Establishment

Name	Address	ID/FEI	Business Operations
Medefil, Inc.		016448669	manufacture(64253-020)

Revised: 1/2023

Medefil, Inc.