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

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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)
(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)
(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

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FULL PRESCRIBING INFORMATION: CONTENTS*
* Sections or subsections omitted from the full prescribing information are not listed.

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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 Pharmaceutic 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:

<table>
<thead>
<tr>
<th>Product</th>
<th>NDC Number</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>1 mL, Single-dose pre-filled syringe, carton of 10s</td>
<td>64523-020-41</td>
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<td>64253-020-71</td>
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<td>Sterile Water for Injection, USP**</td>
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<td>Sterile Water for Injection, USP</td>
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<td>2.5 mL, Single-dose pre-filled syringe, carton of 60s</td>
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<td>Sterile Water for Injection, USP*</td>
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<td>Sterile Water for Injection, USP</td>
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<tr>
<td>10 mL, Single-dose pre-filled syringe, carton of 60s</td>
<td>64253-020-30</td>
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</tbody>
</table>

*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

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.

Medefil, Inc., Glendale Heights, IL 60139
Rev. 001 (03/2020)
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.

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

Medefil, Inc., Glendale Heights, IL 60139
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.

Medefil, Inc., Glendale Heights, IL 60139
Rev. 001 (03/2020)
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.
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

Medefil, Inc., Glendale Heights, IL 60139

L4300 Rev. 000 (12/2019)
3 mL Single-dose pre-filled syringe  NDC 64253-020-23

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.

Medefil, Inc., Glendale Heights, IL 60139

Rev. 001 (03/2020)
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.
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

Medefil, Inc., Glendale Heights, IL 60139

L4301 Rev. 000 (12/2019)
5 mL Single-dose pre-filled syringe  

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.

Medefil, Inc., Glendale Heights, IL 60139

(01) 10364253020350

Rev. 001 (03/2020)

LOT/EXP.
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.
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

Medefil, Inc., Glendale Heights, IL 60139
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.

Medefil, Inc., Glendale Heights, IL 60139
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.

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

Medefil, Inc., Glendale Heights, IL 60139

L4303 Rev. 000 (12/2019)
Sterile Water for Injection, USP
10 mL, Single-dose prefilled syringe

Use Aseptic Technique
1. Remove plastic wrapping by peeling apart.
2. Press the plunger rod forward to relieve any resistance that may be present.
3. Remove tip cap. Press the plunger rod forward until air is expelled from the syringe.

WARNING: NOT ISOTONIC, HEMOLYTIC
Do not give intravenously unless ordered by a physician.
Contains no antimicrobial or other added substances.

Discard unused portion.

Medfit, Inc.
E. 60th St.
Chicago, Ill.

NDC: 64361-020-00
Rx only
5 mL Single-dose pre-filled syringe  NDC 64253-020-25

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.

Medefil, Inc., Glendale Heights, IL 60139
Rev. 000 (03/2020)
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.


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

SEE INSTRUCTIONS
NOT MADE WITH NATURAL RUBBER LATEX
SINGLE USE
STERILE
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 bacteriostatic, 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 (2.0 to 1.5 liters each for inensible 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 Pharmacologic 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 appropriate 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 precipitations 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
STERILE WATER
sterile water for injection injection, solution

Product Information

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.

OVERDOSE:
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 this 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:

<table>
<thead>
<tr>
<th>Product</th>
<th>NDC Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile Water for Injection, USP 1 mL, Single-dose prefilled syringe, carton of 10s</td>
<td>64253-020-41</td>
</tr>
<tr>
<td>Sterile Water for Injection, USP 2.5 mL, Single-dose prefilled syringe, carton of 10s</td>
<td>64253-020-51</td>
</tr>
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<td>Sterile Water for Injection, USP 5 mL, Single-dose prefilled syringe, carton of 10s</td>
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*in 5 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.

Medefl, Inc.
Glendale Heights, IL 60139
L4309 Rev. 002 (09/2020)
### Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
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<tbody>
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<td>WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)</td>
<td>WATER</td>
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### Packaging

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<td>60 in 1 BOX</td>
<td>01/27/2020</td>
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<tr>
<td>1</td>
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<td>1 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
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<td>2</td>
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<td>7</td>
<td>NDC:64253-020-91</td>
<td>10 in 1 BOX</td>
<td>09/21/2020</td>
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<td>7</td>
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<td>10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
<td>09/21/2020</td>
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### Marketing Information

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**Labeler** - Medefil, Inc. (016448669)

**Establishment**
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<th>Business Operations</th>
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Revised: 9/2020