

STERILE WATER- water injection
Fresenius Kabi USA, LLC

Sterile Water for Injection, USP

DESCRIPTION

This preparation is designed solely for parenteral use only after addition to 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 IV injection, add sufficient amount to a solute to make an approximately isotonic solution. pH 5.0 to 7.0.

Water for Injection, USP is chemically designated H₂O.

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

Water balance is maintained by various regulatory mechanisms. Water 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 newborns 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 must be made approximately isotonic prior to use.

WARNINGS

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

Where Water for Injection is required for preparing or diluting medications for use in newborns, only preservative-free Sterile Water for Injection should be used.

PRECAUTIONS

General

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.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle. Consult with pharmacist, if available.

Pregnancy Category C

Animal reproduction studies have not been conducted with Sterile Water for Injection. It is also not known whether Sterile Water for Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection should be given to a pregnant woman only if clearly needed.

Pediatric Use

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

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 newborn 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.

Use aseptic technique for single entry and withdrawal from all containers. Single dose vials should be entered just once.

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.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED:

Product Code	Unit of Sale	Volume	Each
918510	NDC 63323-185-10 Unit of 25	10 mL in a 10 mL vial	NDC 63323-185-07 10 mL Single Dose Vial
918520	NDC 63323-185-20 Unit of 25	20 mL in a 20 mL vial	NDC 63323-185-08 20 mL Single Dose Vial
918550	NDC 63323-185-50 Unit of 25	50 mL in a 50 mL vial	NDC 63323-185-09 50 mL Single Dose Vial

Packaged in a plastic vial. Vials are packaged 25 vials per tray.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Single dose use. No preservative added.

Unused portion of vial should be discarded.

Use only if solution is clear and seal intact.



Lake Zurich, IL 60047

www.fresenius-kabi.com/us

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Revised: July 2021

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 10 mL Single Dose Vial Label

NDC 63323-185-07

918510

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

10 mL Single Dose Vial

NDC 63323-185-07 918510

STERILE WATER
FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

10 mL Single Dose Vial

Sterile, Nonpyrogenic
Preservative Free
Discard unused portion.
Do not administer intravenously unless rendered nearly isotonic.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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LOT/EXP

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 10 mL Single Dose Vial Tray Label

NDC 63323-185-10

918510

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

10 mL Single Dose Vial

25 Vials

NDC 63323-185-10

918510

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

10 mL Single Dose Vial
25 Vials

Sterile, Nonpyrogenic
Preservative Free

Discard unused portion.

Do not administer intravenously
unless rendered nearly isotonic.

Store at 20° to 25°C (68° to
77°F) [see USP Controlled
Room Temperature].

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(01)20363323185101

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 20 mL Single Dose Vial Label

NDC 63323-185-08

918520

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

20 mL Single Dose Vial

NDC 63323-185-08

918520

STERILE WATER

FOR INJECTION, USP

Rx only

FOR DRUG DILUENT USE ONLY

20 mL Single Dose Vial

Sterile, Nonpyrogenic
Preservative Free

Discard unused portion.

Do not administer
intravenously unless
rendered nearly isotonic.
See insert.

Store at 20° to 25°C
(68° to 77°F) [see USP
Controlled Room
Temperature].

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LOT/EXP

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 20 mL Single Dose Vial Tray Label

NDC 63323-185-20

918520

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

20 mL Single Dose Vial

25 Vials

NDC 63323-185-20 918520

STERILE WATER
FOR INJECTION, USP

Rx only

FOR DRUG DILUENT USE ONLY

20 mL Single Dose Vial
25 Vials

Sterile, Nonpyrogenic
Preservative Free
Discard unused portion.


Do not administer intravenously unless rendered nearly isotonic.

See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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(01)20363323185200

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 50 mL Single Dose Vial Label

NDC 63323-185-09

918550

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

50 mL Single Dose Vial

NDC 63323-185-09 918550

STERILE WATER
FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

50 mL Single Dose Vial


Sterile, Nonpyrogenic
Preservative Free
Discard unused portion.

Do not administer intravenously unless rendered nearly isotonic.

See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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LOT/EXP

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 50 mL Single Dose Vial Tray Label

NDC 63323-185-50

918550


STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

50 mL Single Dose Vial

25 Vials

NDC 63323-185-50	918550
<p>STERILE WATER <i>FOR INJECTION, USP</i></p> <p>FOR DRUG DILUENT USE ONLY</p> <p>Rx only</p> <p>50 mL Single Dose Vial 25 Vials</p>	
<p>Sterile, Nonpyrogenic Preservative Free</p> <p>Discard unused portion.</p> <p>Do not administer intravenously unless rendered nearly isotonic.</p> <p>See insert.</p> <p>Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].</p>	<p>Fresenius Kabi Lake Zurich, IL 60047 www.fresenius-kabi.com/us</p> <p>4 2 7 1 6</p>  <p>(01)20363323185507</p>

STERILE WATER				
water injection				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63323-185	
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1 mL in 1 mL		
Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:63323-185-10	25 in 1 TRAY	09/05/2000	
1	NDC:63323-185-07	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:63323-185-50	25 in 1 TRAY	09/05/2000	
2	NDC:63323-185-09	50 mL in 1 VIAL; Type 0: Not a Combination Product		
3	NDC:63323-185-20	25 in 1 TRAY	09/05/2000	
3	NDC:63323-185-08	20 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088400	09/05/2000	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	manufacture(63323-185) , analysis(63323-185)

Revised: 9/2021

Fresenius Kabi USA, LLC