STERILE WATER- water injection
Fresenius Kabi USA, LLC
Reference Label Set Id: b77a85a8-dff3-40c5-aa4d-941aaf006e57

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 H_2O.

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 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.

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.

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

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.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

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

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
187100	NDC 65219-187-10 Unit of 25	100 mL in a 100 mL vial	NDC 65219-187-01 100 mL Single Dose Vial
18505	NDC 63323-185-05 Unit of 25	5 mL in a 6 mL vial	NDC 63323-185-04 5 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

45768H
Revised: April 2022

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

NDC 63323-185-07

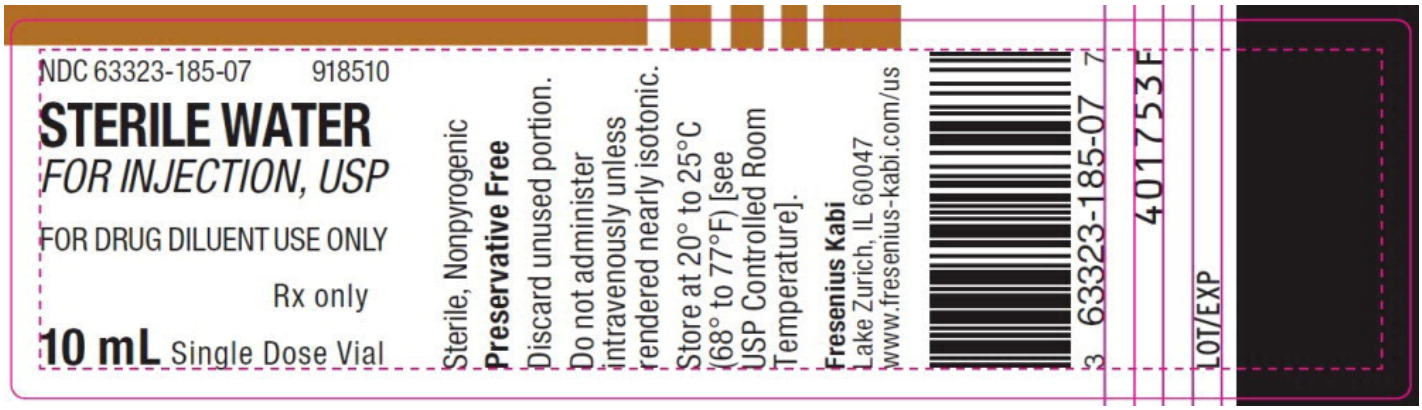
918510

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

10 mL Single Dose Vial



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

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

NDC 63323-185-08

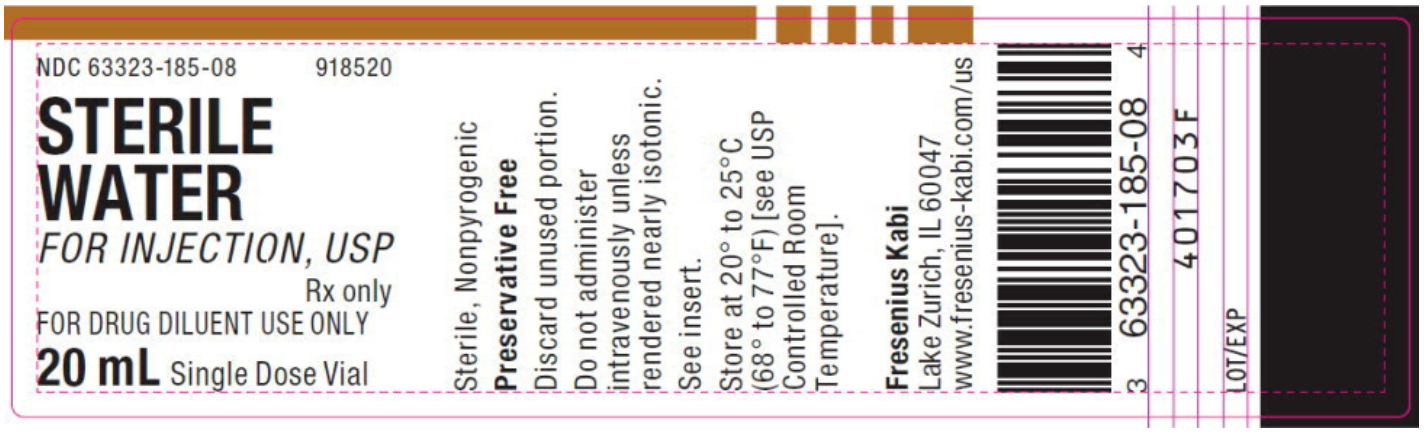
918520

STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

20 mL Single Dose Vial



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

NDC 63323-185-20

918520

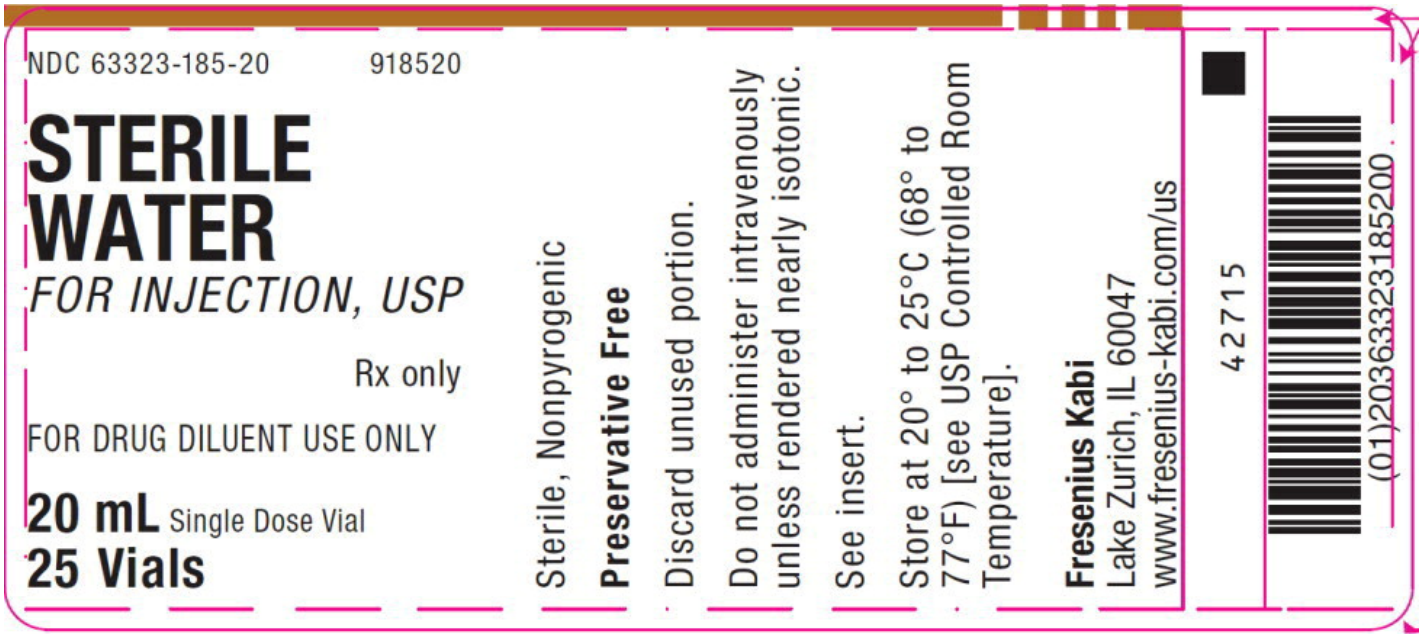
STERILE WATER FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

20 mL Single Dose Vial

25 Vials



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

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

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 5 mL Single Dose Vial Label

NDC 63323-185-04

18505

STERILE WATER

FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

5 mL Single Dose Vial

PACKAGE LABEL - PRINCIPAL DISPLAY - STERILE WATER - 5 mL Single Dose Tray Label

NDC 63323-185-05

18505

STERILE WATER

FOR INJECTION, USP

FOR DRUG DILUENT USE ONLY

Rx only

5 mL Single Dose Vial

25 Vials

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 Date	Marketing End 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		
4	NDC:63323-185-05	25 in 1 TRAY	04/30/2022	
4	NDC:63323-185-04	5 mL in 1 VIAL, SINGLE-DOSE; 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: 6/2022 Fresenius Kabi USA, LLC