STERILE WATER- water injection, solution
ICU Medical Inc.

Sterile Water for Injection, USP

FOR DRUG DILUENT USE ONLY

Flexible Plastic Container

Rx only

DESCRIPTION

Sterile Water for Injection, USP is a sterile, nonpyrogenic, solute-free preparation of distilled water for injection. It is for use only as a sterile solvent or diluent vehicle for drugs or solutions suitable for parenteral administration. The pH is 5.5 (5.0 to 7.0).

Sterile Water for Injection contains no bacteriostat, antimicrobial agent or added buffer and is intended only for single-dose injection after admixture with an appropriate solute or solution. When smaller amounts are required, the unused portion should be discarded.

Sterile Water for Injection is a pharmaceutic aid (vehicle) and parenteral fluid replenisher after addition of an appropriate solute.

Water for Injection, USP is chemically designated H_2O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions inside the plastic container also can leach out certain chemical components of the plastic in very small amounts before the expiration period is attained. However, the safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers.

CLINICAL PHARMACOLOGY

When administered intravenously as a vehicle for drugs, sterile water for injection provides a source of water for parenteral fluid replenishment after sufficient solute is introduced to achieve an osmolarity of 112 mOsmol or more per liter.

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 distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

Sterile Water for Injection, USP is indicated for use only as a solvent or diluent vehicle for parenterally administered drugs or solutions and as a source of water for parenteral fluid replenishment after suitable additives are introduced.

For intravenous administration, an osmolar concentration not less than two-fifths (0.4) of the normal osmolarity of the extracellular fluid (280 mOsmol/liter) is essential to avoid intravascular hemolysis.

CONTRAINDICATIONS

Do not administer without the addition of a solute.

WARNINGS

FOR DRUG DILUENT USE ONLY.

Intravenous administration of Sterile Water for Injection, USP without additives may result in hemolysis.

The intravenous administration of sterile water for injection with additives can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

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 use for intravenous injection unless the osmolar concentration of additives totals at least 112 mOsmol/liter (two-fifths of the normal osmolarity of the extracellular fluid — 280 mOsmol/liter).

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

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: 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.

This product contains no more than 25 mcg/L of aluminum.

ADVERSE REACTIONS

Reactions which may occur because of the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. (See ***WARNINGS***.)

DOSAGE AND ADMINISTRATION

Following suitable admixture of prescribed additive, the dose is usually dependent upon the age, weight and clinical condition of the patient.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

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

HOW SUPPLIED

Sterile Water for Injection, USP is supplied in a single-dose 1000 mL flexible plastic container (NDC 0409-7990-09[1,2] and 0990-7990-09[1,2]).

ICU Medical is transitioning NDC codes from the "0409" to a "0990" labeler code. Both NDC codes are expected to be in the market for a period of time.

INSTRUCTIONS FOR USE

To Open

Tear outer wrap at notch and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish

gradually.

To Add Medication

1. Prepare additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive port may be protected by covering with an additive cap.
4. Mix container contents thoroughly.

Preparation for Administration

(Use aseptic technique)

1. Close flow control clamp of administration set.
2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated. **NOTE:** See full directions on administration set carton.
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open flow control clamp and clear air from set. Close clamp.
7. Attach set to venipuncture device. If device is not indwelling, prime and make venipuncture.
8. Regulate rate of administration with flow control clamp.

WARNING: DO NOT USE FLEXIBLE CONTAINER IN SERIES CONNECTIONS.

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

Revised: September, 2018

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA EN-4689

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1 Manufactured by ICU Medical, Inc., Lake Forest, Illinois, 60045, USA
2 Manufactured for ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label

1000 mL

NDC 0990-7990-09

STERILE WATER
for Injection, USP

DO NOT GIVE INTRAVENOUSLY.
FOR DRUG DILUENT USE ONLY.

CONTAINS NO ANTIMICROBIAL OR OTHER
SUBSTANCE.

ADMIXTURES SHOULD BE USED PROMPTLY

WITH ADEQUATE PRECAUTIONS FOR
MAINTAINING STERILITY.

WARNINGS: NOT ISOTONIC.
HEMOLYTIC.

ADDITIVES MAY BE INCOMPATIBLE.
CONSULTATION WITH A PHARMACIST IS
RECOMMENDED. WHEN INTRODUCING
ADDITIVES, USE ASEPTIC TECHNIQUE,
MIX THOROUGHLY AND DO NOT STORE.

SINGLE-DOSE CONTAINER. FOR INTRAVENOUS USE. DO
NOT GIVE INTRAVENOUSLY UNLESS RENDERED NEARLY
ISOTONIC. USUAL DOSAGE: SEE INSERT. STERILE,
NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR
AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN
SERIES CONNECTIONS. pH 5.5 (5.0 to 7.0)

RX ONLY

3
V
CONTAINS DEHP

icumedical

IM-4423

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

1000 mL ⊕ NDC 0990-7990-09

STERILE WATER

for Injection, USP

DO NOT GIVE INTRAVENOUSLY.
FOR DRUG DILUENT USE ONLY.

CONTAINS NO ANTIMICROBIAL OR OTHER SUBSTANCE.

ADMIXTURES SHOULD BE USED PROMPTLY WITH ADEQUATE PRECAUTIONS FOR MAINTAINING STERILITY.

WARNINGS: NOT ISOTONIC. HEMOLYTIC.

ADDITIVES MAY BE INCOMPATIBLE. CONSULTATION WITH A PHARMACIST IS RECOMMENDED. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

SINGLE-DOSE CONTAINER. FOR INTRAVENOUS USE. DO NOT GIVE INTRAVENOUSLY UNLESS RENDERED NEARLY ISOTONIC. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS. pH 5.5 (5.0 to 7.0)

Rx ONLY LATEX 3 V CONTAINS DEHP icumedical

IM-4423

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA ⊕

1 2 3 4 5 6 7 8 9

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Overwrap

2
HDPE

TO OPEN TEAR AT NOTCH

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.
98-4321-R14-3/98

STERILE WATER
water injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7990
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1000 mL in 1000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7990-09	12 in 1 CASE	10/01/2019	
1		1 in 1 POUCH		
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
NDA	NDA018233	10/01/2019	

Labeler - ICU Medical Inc. (118380146)

Revised: 7/2019 ICU Medical Inc.