STERILE WATER- sterile water injection
Nephron Pharmaceuticals Corporation

Sterile Water for Injection, USP

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, dissolve sufficient solute to make an approximately isotonic solution. Water for Injection, USP is chemically designated H_2O. pH 5.0 to 7.0.

The plastic single-dose vial is fabricated from polypropylene resin. The plastic vials feature a twist-off cap which, when removed, allows access to a luer-lock fitting for connection to a luer-lock syringe. The twist-off cap is a one-time use tamper evident feature, and the container vial cannot be reclosed once the cap is removed.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight.

Average 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 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 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.

Animal reproduction studies have not been conducted with Sterile Water for Injection. It is not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or 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, when combined in the same vehicle, or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

Use aseptic technique for withdrawal from the container. 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.

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.

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.**

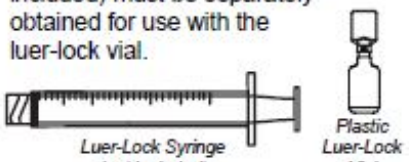
The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose, and route of administration as recommended by the manufacturer. This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Please refer to INSTRUCTIONS FOR USE for administration instructions.

Sterile Water for Injection, USP is supplied in 5 mL vials, packaged in cartons as follows: NDC 0487-6105-01, 30 individual 5 mL single-dose luer-lock vials.

Discard unused portion. Each vial is made from a polypropylene (PP) resin. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

INSTRUCTIONS FOR USE
Sterile Water for Injection, USP
5 mL Single-Dose Luer-Lock Vial
Read complete instructions carefully before using.

USE ASEPTIC TECHNIQUE
A sterile luer-lock syringe (not included) must be separately obtained for use with the luer-lock vial.



Use aseptic technique throughout the following steps for the withdrawal of the contents from the luer-lock vial.

INSTRUCTIONS FOR USE
Sterile Water for Injection, USP
Luer-Lock Vial

① Hold the vial firmly while twisting off the cap to expose the luer-lock fitting.

② Draw the plunger back on a luer-lock syringe.

③ Connect the syringe to the vial, twisting clockwise, using the luer-lock connection.

④ Charge the vial with air by fully depressing the plunger.

⑤ Orient the assembly so that the syringe is pointing up and draw the product into the syringe.

⑥ Disconnect the syringe from the vial and connect the syringe to the final point of use.

⑦ Discard unused portion.

IC 2023
Rev 03-23-21
Manufactured by:
nephron
West Columbia, SC 29172
1-800-443-4313

Sterile Water for Injection, USP 5 mL Single-Dose Luer-Lock Vial Read complete instructions carefully before using. USE ASEPTIC TECHNIQUE and instructions for use. A

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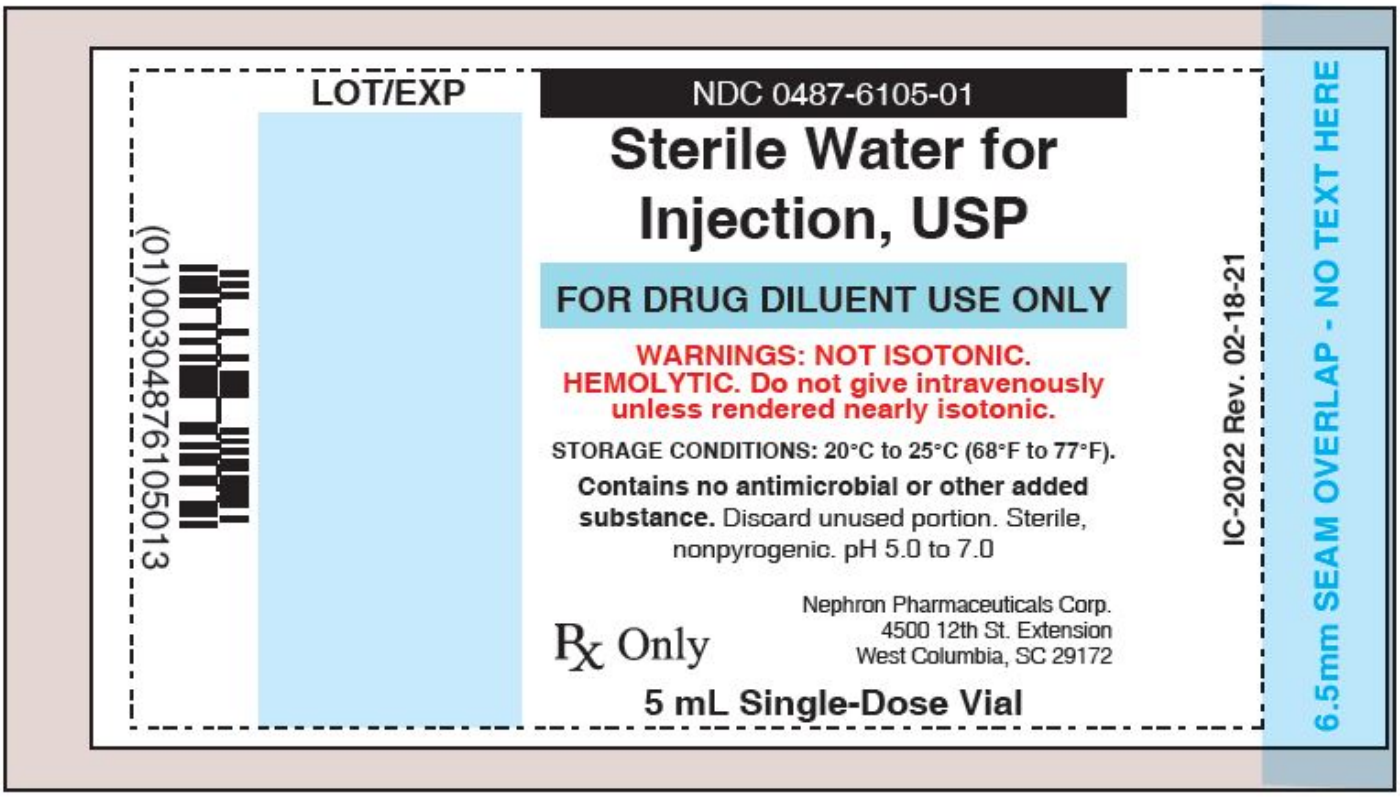

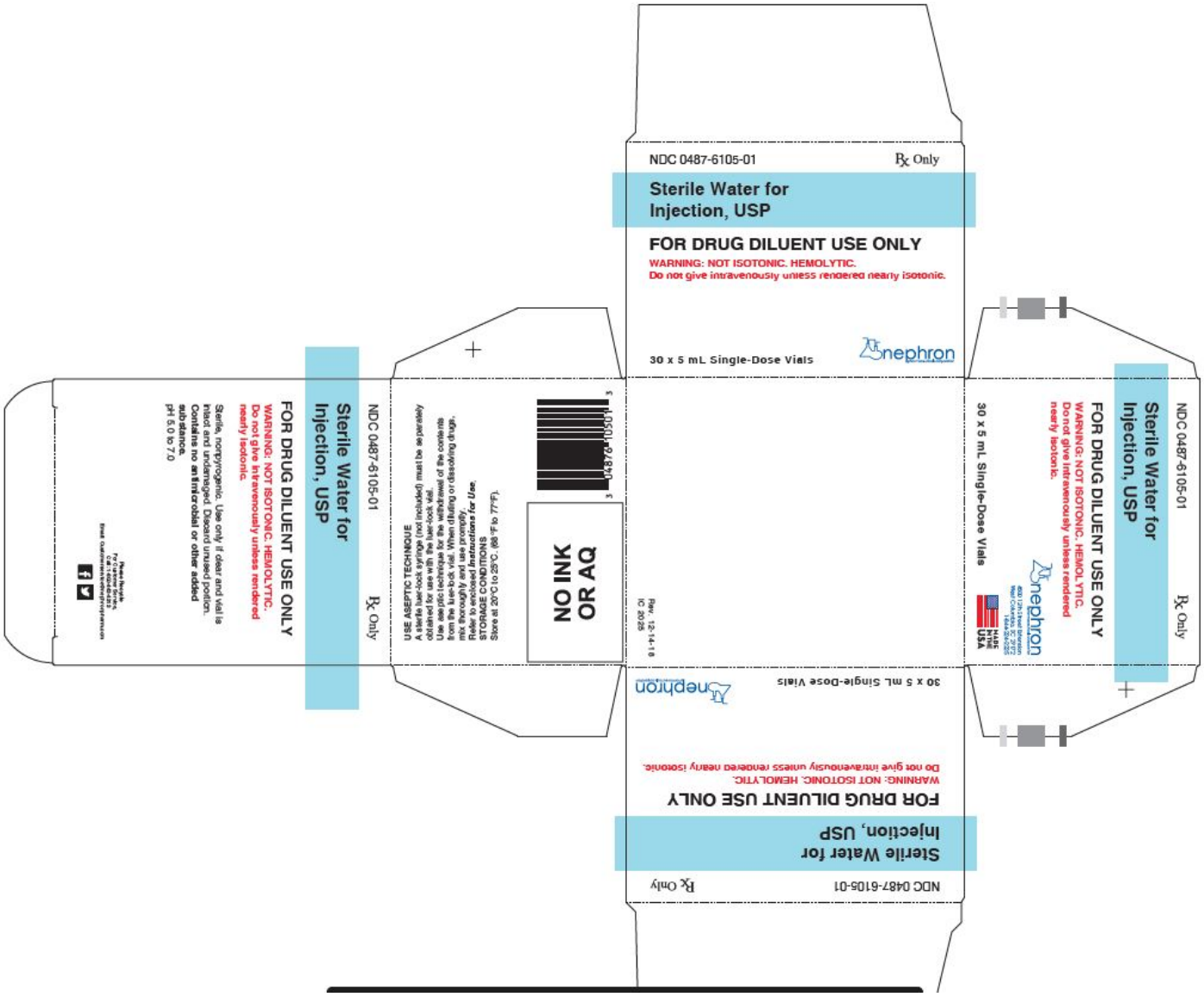

STERILE WATER

sterile water injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0487-6105
Route of Administration	INTRAVENOUS, INTRAMUSCULAR, SUBCUTANEOUS		

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:0487-6105-01	30 in 1 CARTON	06/16/2021	
1		5 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211222	06/07/2021	

Labeler - Nephron Pharmaceuticals Corporation (079160190)

Registrant - Nephron SC Inc. (079160190)

Establishment

Name	Address	ID/FEI	Business Operations
Nephron SC Inc.		079160190	manufacture(0487-6105) , analysis(0487-6105) , label(0487-6105) , pack(0487-6105) , sterilize(0487-6105)

Revised: 6/2021 Nephron Pharmaceuticals Corporation