

WATER- water injection

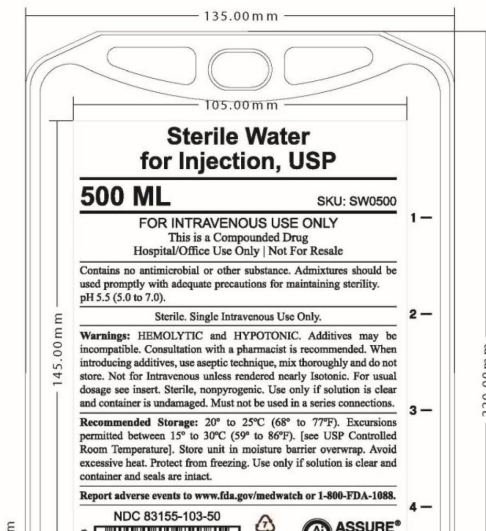
Assure Infusions, Inc.

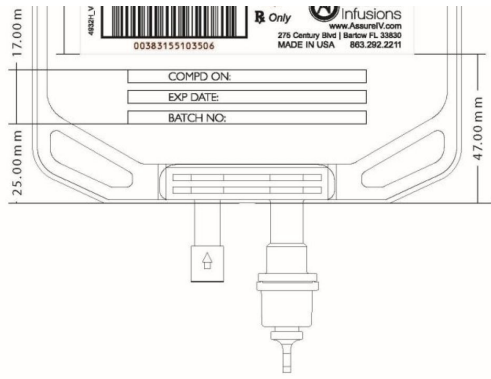
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SterileWater250



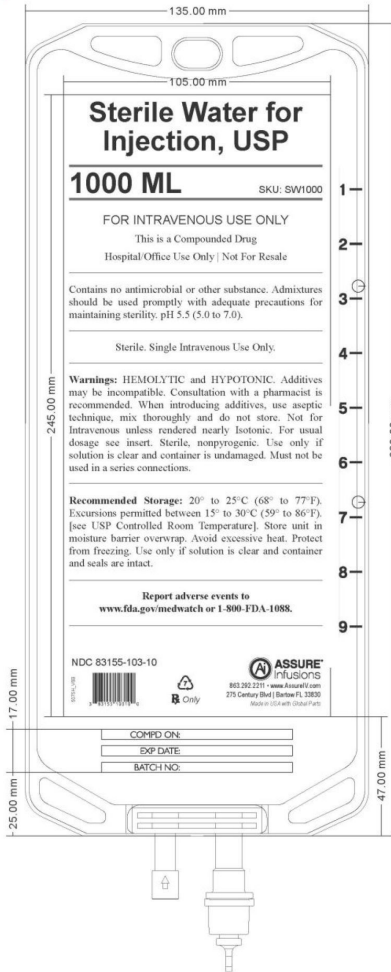
250 mL Sterile WFI Label.jpg





500 mL Sterile WFI Label.jpg

SterileWater1000



1000 mL Sterile WFI Label.jpg

HEMOLYTIC and HYPOTONIC. Additives may be incompatible. Consultation with a pharmacist is recommended. When introducing additives, use aseptic technique, mix thoroughly and do not store. Not for Intravenous unless rendered nearly Isotonic. For usual dosage see insert. Sterile, nonpyrogenic. Use only if solution is clear and container is undamaged. Must not be used in a series connections.

Purpose:

This product is being distributed in response to a shortage of Sterile Water For Injection, USP product in the United States as per U.S. Food and Drug; FDA Drug Shortgae List.

Regulatory Status:

This product has not been approved by the U.S. Food and Drug Administration but is being made available under enforcement discretion during a drug shortage.

Product Description:

This product only have Water for Injection, USP.

Dosing and Administration:

The route of administration is intravenous. Product is not for direct intravenous use unless rendered nearly Isotonic. It can be used as a drug diluent. Following suitable admixture of prescribed additive, the final product dose is usually dependent upon the age, weight and clinical condition of the patient.

Safety Information:

Additives may be incompatible. Please confirm compatibility.

Storage and Handling:

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

Reporting Adverse Events:

Report adverse events to www.fda.gov/medwatch or 1-800-FDA-1088.

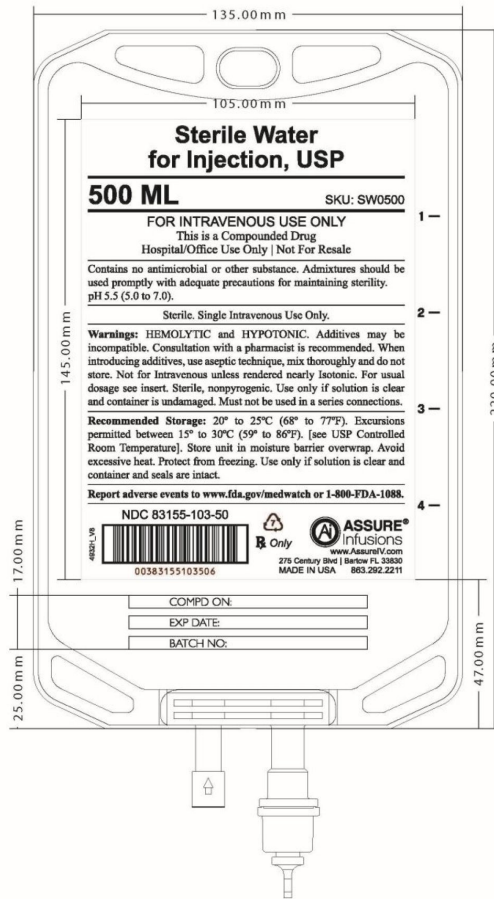
Contact Information:

For any question or concern, please contact 1-863-292-2211. Email: Info@AssureIV.com.

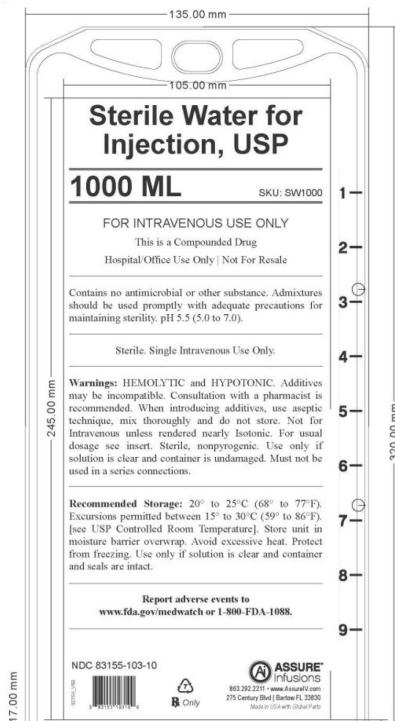
Package Label

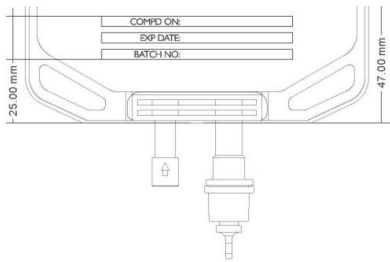
SterileWater250





SterileWater1000





1000 mL Sterile WFI Label.jpg

WATER

water injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:83155-103
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	250 mL in 250 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83155-103-50	500 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/16/2026	
2	NDC:83155-103-25	250 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/16/2026	
3	NDC:83155-103-10	1000 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/16/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		04/16/2026	

Labeler - Assure Infusions, Inc. (053016941)

Registrant - Assure Infusions, Inc. (053016941)

Establishment

Name	Address	ID/FEI	Business Operations
Assure Infusions, Inc.		053016941	manufacture(83155-103)

