

VETERINARY STERILE WATER - sterile water injection
Ivali LLC

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.

Veterinary Sterile Water For Injection, USP

For Animal Use Only

Indications

Veterinary Sterile Water for Injection is suitable for use as a diluent for the preparation of pharmaceutical solutions

Description

Prepared by distillation. Contains no antimicrobial agents or other substance has been added. Discard unused portion. Sterile, nonpyrogenic. Osmolarity and pH are shown in Table 1:

TABLE 1

Veterinary Sterile Water for Injection, USP	
Size (mL)	1000
Osmolarity (mOsmol/L) (calc)	0
pH	5.5 (5.0 to 7.0)

Contraindications :

None known

Warnings

This solution is not isotonic and is hemolytic.

Dosage and administration:

As directed by a veterinarian.

Cautions

Sterile water for Injection is not suitable for intravascular injection without first having been made isotonic by addition of suitable solutes. Do not use unless solution is clear and seal is intact. Discard unused portion.

How Supplied:

Veterinary Sterile Water for Injection, USP in plastic container is available as follows:

NDC Code	Size (mL)	Product Name
86094-891-01	1000	Sterile Water For Injection, USP

Plastic Container:PVC Free, DEHP Free, Latex Free. The volumetric scales on the single dose plastic container should only be used as a reference. For precise dosage of volumes it is recommended the use of IV Infusion pump or IV Burette.

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored in the moisture overwrap at room temperature (25⁰C/77⁰F), brief exposure up to (40⁰C/104⁰F) does not adversely affect the product.

Directions for use of plastic container

To Open

Tear overwrap down side at slit and remove solution container. 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. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

Not for injection, for irrigation only.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian



Manufactured for:

IVALI LLC

18205 Biscayne Blvd., Suite 2202
Aventura Florida

Printed in Argentina

For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call IVALI LLC. Customer service at 1-305-692-7665

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Principal Display Panel

NDC 86094-891-01

IVALI

Veterinary Sterile Water for Injection, USP

1000 mL

NDC 86094-891-01	---
IVALI™	---
Veterinary Sterile Water	1
Injection, USP	2
PREPARED BY DISTILLATION. CONTAINS: NO ANTIMICROBIAL	---

AGENTS OR OTHER SUBSTANCE HAS BEEN ADDED. pH 5.5 (5.0 TO 7.0). OSMOLARITY: 0 mOsmol/L (CALC.).
STERILE NONPYROGENIC. WARNING: THIS SOLUTION IS NOT ISOTONIC AND IS HEMOLYTIC. DOSAGE AND ADMINISTRATION: AS DIRECTED BY A VETERINARIAN. SEE PACKAGE INSERT CAUTIONS. DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT. DISCARD UNUSED PORTION. INDICATIONS: STERILE WATER FOR INJECTION IS SUITABLE FOR USE AS DILUENT FOR PREPARATION OF PHARMACEUTICAL SOLUTIONS. CAUTION: STERILE WATER FOR INJECTION IS NOT SUITABLE FOR INTRAVASCULAR INJECTION WITHOUT FIRST HAVING BEEN MADE ISOTONIC BY ADDITION OF SUITABLE SOLUTES. STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE. AVOID EXCESSIVE HEAT.

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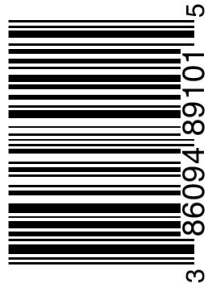
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FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

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1000 mL

8

TAKE TIME  OBSERVE LABEL DIRECTIONS



Rev.04/18

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MANUFACTURED FOR:

IVALI™

Made in Argentina

18205 Biscayne Blvd., Suite 2202
 Aventura, FL 33160

VETERINARY STERILE WATER

sterile water injection

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86094-891
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	100 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86094-891-01	1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/11/2018	

Labeler - Ivali LLC (081136076)**Establishment**

Name	Address	ID/FEI	Business Operations
LABORATORIOS JAYOR S.R.L.		979312485	api manufacture, manufacture

Revised: 5/2018

Ivali LLC