

**0.9% SODIUM CHLORIDE IRRIGATION- blue pharma, totalcare, 0.9% sodium chloride irrigation irrigant
AMCO INTERNATIONAL CORP**

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.

Directions for Use of Flexible Plastic Irrigation Containers

If desired, warm in overwrap to near body temperature in a water bath or oven heated to not more than 45°C. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

DIRECTIONS FOR USE

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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 bag firmly. If leaks are found, discard solution as sterility may be impaired. Use Aseptic Technique. 1.Suspend container using hanger hole. 2.Remove plastic protector from outlet port at bottom of container 3.Attach irrigation set. Refer to complete directions accompanying set. Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C): brief exposure up to 40°C does not adversely affect the product

Dear Healthcare Professional,

To prevent a drug shortage of large volume parenteral fluid drug products, we plan to coordinate with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride IRRIGATION (3,000 mL) from specific DRE manufacturing facilities. FDA has not approved these products manufactured by this facility. We are also working to label and produce this drug domestically in the United States.

You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because each letter may contain different product specific information.

All labels are in English with NDC listed on label.

It is important to note the following:

After opening the carton or box, the bags should be inspected visually to confirm there is no visible particulate matter or bag defects, such as leaks. Container integrity is imperative to ensure sterility of products. Parenteral drug products should be inspected visually for particulate matter and bag defects prior to administration, whenever solution or container permits.

USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE IV BAG CONTAINS A LEAK.

Reporting Adverse Events or Product Quality Issues

To report adverse events associated with these imported products, please call AMCO

at+1 833 3 MY AMCO.

. Adverse events or quality problems experienced with the use of these imported products may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call

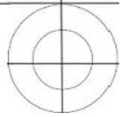
1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

To report product quality issues associated with these imported products, please contact AMCO at +1 833 3 MY AMCO.

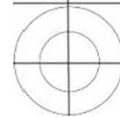
If you have any questions about the information contained in this letter or the use of the imported products, please Contact +1 833 3 MY AMCO.

To place an order, please contact AMCO at +1 833 3 MY AMCO.

3000 mL NDC NOT FOR INJECTION 0.9% SODIUM CHLORIDE Irrigation USP Each 100 mL contains 900 mg Sodium Chloride USP No antimicrobial agent has been added pH 5.5 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolarity 308 mOsmol/L (calc) Sterile Nonpyrogenic Single dose container Do not use unless solution is clear Discard unused portion Cautions Squeeze and inspect inner bag which maintains product sterility Discard if leaks are found Rx Only Store unit in moisture barrier overwrap at room temperature (25°C) until ready to use Avoid excessive heat See insert 0.9% Sodium Chloride NaCl Irrigation USP



NDC XXXXXX



TotalCare

3000 mL

0.9% Sodium Chloride Irrigation, USP

Not for injection.

Rx only

100

Each 100 mL contains: Sodium Chloride 900 mg
in water for injection.

Electrolytes per 1,000 mL:

Sodium	154 mEq
Chloride	154 mEq
308 mOsmol/LITER (CALC.)	pH 4.5 to 7.0

200

Single Dose Only. Discard Unused Portion.

Additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique, mix thoroughly and do not store. Use only if solution is clear and container is undamaged. Must not be used in series connections.

300

Usual dosage: See package insert.

STORE AT: 25°C (77°F) [see USP Controlled Room Temperature]. Protect from freezing.

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

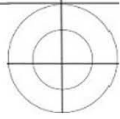
400

BARCODE HERE

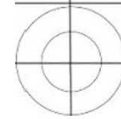
MFG BY:

AMCO INTERNATIONAL
CORP

EXP
LOT#



NDC XXXXXX



TotalCare

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MFG BY:

AMCO INTERNATIONAL
CORP

EXP
LOT

blue pharma, totalcare, 0.9% sodium chloride irrigation irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84866-6670
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84866-6670-4	10 in 1 CARTON	12/16/2024	
1	NDC:84866-6670-1	3000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/16/2024	

Labeler - AMCO INTERNATIONAL CORP (116924852)

Establishment

Name	Address	ID/FEI	Business Operations
AMCO INTERNATIONAL CORP		116924852	manufacture(84866-6670)

Revised: 12/2024

AMCO INTERNATIONAL CORP