

## PRODUCT INFORMATION NOTICE

# NaturaLyte<sup>®</sup> Bicarbonate Product

## Changes to name, packaging, and storage instructions

### Dear Valued Customer,

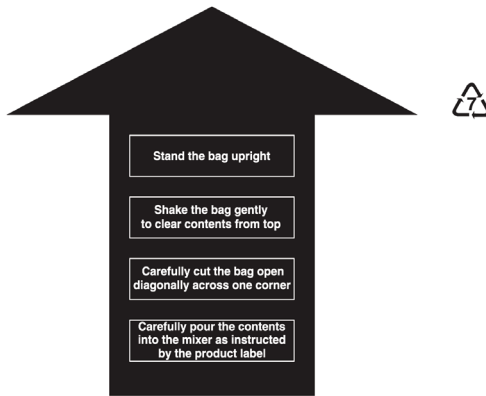
Updates have been made to the name, packaging, and storage instructions for the NaturaLyte<sup>®</sup> 4000 Series Dry Pack for Bicarbonate Rx-10 (Catalog No. 08-4110-6) and Bicarbonate Carton (Catalog No. 08-4400-1).

- The 4000 is being removed from the product name.
- The updates to packaging include:
  - A change in print color on the package to help differentiate between the Rx-10 and the Rx-12 bags.
    - Rx-10 has black printing and a black dual band along with a black arrow, while Rx-12 has blue printing and a blue dual band along with a blue arrow.
    - The location of the product bar code has been moved to the top section of the new bag.
  - Storage and temperature exposure range has also been updated.
- The updated product is identical to the current product and the product ordering numbers have not changed.

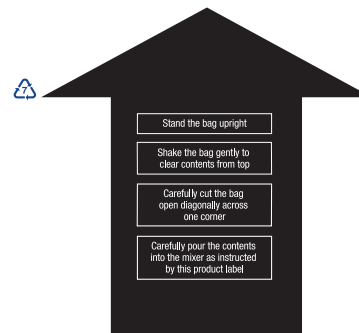
▶ See following pages for details

Changes include:

Old Package: Rx-10



New Package: Rx-10



**WARNING:** For use only with three-stream proportioning bicarbonate systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated acid concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Catalog No. 08-4110-6

**45x** **NaturaLyte® 4000 Rx-10**  
Dry Pack for Bicarbonate Dialysis

**Ionic Composition of Bicarbonate concentrate:**  
(Nominal dilution 1:1.72:42.28)  
**Sodium 37 mEq/L**  
**Bicarbonate 37 mEq/L**

One bag of NaturaLyte® 4000 Rx-10 dry pack, when used in conjunction with NaturaLyte® 4000 Series Acid formulation or equivalent, will produce enough dialyzing fluid for approximately ten 5.3 hour time periods at a maximum flow rate of 500 ml/min.

**Chemical Composition:**  
4879 g. Sodium Bicarbonate, U.S.P., Dissolved 81.3 g/L.

**Caution:** Federal (USA) law restricts this device to sale by or on order of a physician.

**DO NOT USE IF PACKAGING IS DAMAGED OR BAG SEAL IS BROKEN.**  
**RECOMMENDED STORAGE:**  
**PROTECT FROM EXCESSIVE HEAT AND FREEZING.**

Fresenius Medical Care  
Waltham, MA 02451  
Fresenius Medical Care 1-800-323-5188

**Directions for Use:**

- To mix NaturaLyte® 4000 Rx-10 dry pack, add 55 liters of purified water to the NaturaLyte® Mixer (Cat. No. 150406) or equivalent container with approx. 70 liter capacity. Container must be free of bacterial and chemical contamination (current AAMI). Use purified water that meets or exceeds current AAMI hemodialysis water quality standards. Water temperature should be 24°C ±2°C.
- Empty entire NaturaLyte® 4000 Rx-10 dry pack into the water gradually while gently mixing the solution. Mix for 1 minute after the powder has been added. **NOTE:** Do not overmix. Vigorous mixing can drive carbon dioxide from the solution and is not recommended. If mixing is manual, it may be easier to dissolve one-third of the bag at a time. Use entire contents of bag.
- Add water for a total volume of 60 liters. Mix again for approx. 10 minutes. Ensure that the powder is dissolved in solution.
- Refer to the directions for use provided in the dialysis machine operator's manual regarding the use of bicarbonate concentrate. Check conductivity and pH of dialyzing fluid before starting treatment and each time solution is added (current AAMI).

**NOTE:** This bicarbonate base concentrate should be used within 24 hours of mixing. Storage in a closed container is recommended to minimize CO<sub>2</sub> loss and resulting precipitation in dialysis equipment. Bacterial growth may occur when using bicarbonate concentrate.

71-1498.01 01/10

**NaturaLyte® Dry Bicarbonate Concentrate For Bicarbonate Hemodialysis**

Catalog No. 08-4110-6 **Rx - 10** **45X**  
60 LITER MIX (15.85 GALLONS) 'B' CONCENTRATE

**Bicarbonate Concentrate Chemical Composition**  
SODIUM BICARBONATE USP 4879 g Dissolved 81.3 g/L

**Ionic Contribution of Liquid Bicarbonate Concentrate to Dialysate**  
(Nominal Dilution 1:1.72:42.28, Acid to Bicarbonate to Water)  
SODIUM 37mEq/L BICARBONATE 37mEq/L

**INDICATIONS FOR USE**  
NaturaLyte Dry Bicarbonate Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. NaturaLyte Dry Bicarbonate Concentrate is intended to be used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription.

**WARNING**

- Failure to follow the Directions for Use may cause patient injury or death.
- Check conductivity and pH of final dialysate prior to dialysis treatment and each time new concentrate is supplied to the machine. Use of a dilute with incorrect conductivity or pH can cause serious injury or death. Refer to hemodialysis machine manufacturer's instructions to determine conductivity and pH of final dialysate.
- Use the prepared solution within 24 hours of mixing. Store in a closed container to minimize contamination. Bacterial growth can occur when using bicarbonate concentrate.
- Mixer/Container must be free of bacterial and chemical contamination per ISO 23500. Use of a contaminated mixer/container to mix concentrate may result in patient injury or death.

**CAUTION**

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Do not use if the package is open or damaged.
- Eye protection must be worn when handling and mixing this product.
- Ensure that all sodium bicarbonate powder is completely dissolved in a final volume of 60 liters before connecting or transferring to a Hemodialysis Machine. For mixing, water temperatures should be between 20°C and 30°C. Water temperature may affect how quickly the powder dissolves in solution. Use of a 'B' (bicarbonate) concentrate with incorrect composition can cause patient injury.

**REQUIREMENTS**

- For use only with three-stream proportioning machines when calibrated to proportion 1 part acid to 1.72 parts bicarbonate concentrate to 42.28 parts purified water that meets ISO 13959 or AAMI R902 water quality requirements.
- For use only with 45x acid (A) concentrate.

**DIRECTIONS FOR USE**

One bag of NaturaLyte Rx-10 will produce enough bicarbonate concentrate for approximately ten 5.3 hour treatments at a maximum flow rate of 500 mL/min.

One bag of NaturaLyte Rx-10, when mixed according to directions, produces 60 liters of bicarbonate concentrate.

- To mix NaturaLyte Rx-10 dry pack, add 55 liters of purified water to a mixer or container with at least 70 liters capacity. Use purified water that meets ISO 13959 or AAMI R902 quality requirements.
- Empty the entire NaturaLyte Rx-10 dry pack into the water gradually while gently mixing the solution. Mix for 1 minute after the powder has been added. If mixing is manual, it may be easier to dissolve one-third of the bag at a time. Use entire contents of bag. Add purified water to total volume of 60 liters. Mix again until the powder is **completely dissolved** in solution (approximately 10 minutes). Record the date and time of mixing.

**NOTE:** Do not overmix. Overmixing can drive carbon dioxide from the solution and is not recommended.

3) Refer to the directions for use provided in the dialysis machine operator's manual regarding the use of bicarbonate concentrate.

**NOTE:** Store in a closed container to minimize CO<sub>2</sub> loss.

**STORAGE**  
Store in a dry location between 5°C and 30°C (41°F and 86°F). Product can withstand an exposure to temperatures down to 0°C and up to 40°C (32°F to 104°F) for a period up to 72 hrs.

71-1498.02 10/19

**FRESENIUS MEDICAL CARE**  
RENAL THERAPIES GROUP

Manufactured by:  
Fresenius Medical Care  
Renal Therapies Group, LLC  
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Waltham, MA 02451 U.S.A.  
1-800-323-5188  
71-1498.02 10/19

Note: Black Arrow, Rx-10 printed in black with white background and black dual stripe

Note: Change in location of bar code

Changes to the storage instructions include:

- New storage temperature range
- New temperature exposure duration

	Old Packaging	New Packaging
<b>Storage Temperature</b>	Protect from excessive heat and freezing	Provides a storage temperature range: 5°C and 30°C (41°F and 80°F)
<b>Temperature Exposure</b>	None	Provides a temperature Exposure range: 0°C and up to 40°C (32°F and 104°F) for a period of 72 hours

**NaturaLyte Dry Pack for Bicarbonate Dialysis carton, Product Number 08-4400-1.**

The updates include a change in the product description to NaturaLyte Dry Pack for Bicarbonate Dialysis carton, revision to mixing instructions and the **blue** carton color. The updated product is identical to the current product and the product ordering number have not changed.

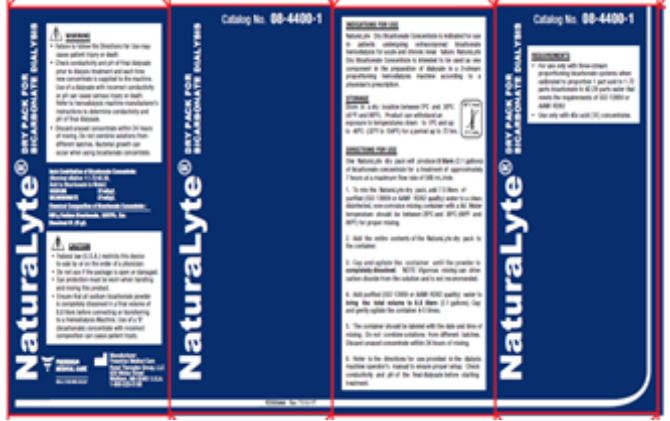
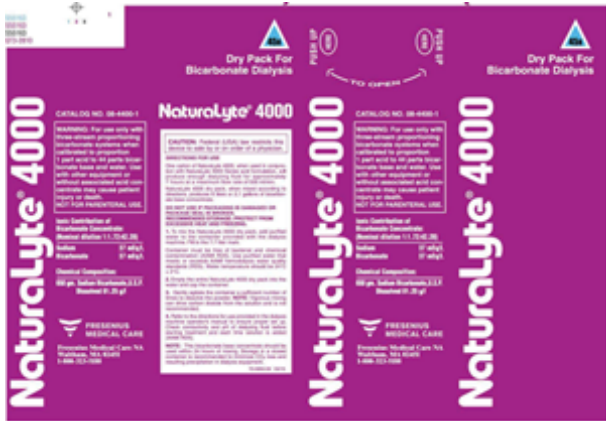
- ▶ Revised instructions must be reviewed and understood by all staff who prepare bicarbonate from the carton prior to continuing use.

Changes include:

	Old Carton	New Carton
Name	NaturaLyte 4000 Dry Pack for Bicarbonate Dialysis	NaturaLyte Dry Pack for Bicarbonate Dialysis

Old Carton: Rx-12

New Carton: Rx-12



Changes to the storage instructions include:

	Old Packaging	New Packaging
<b>Topic</b>	Old Instructions (Pink Carton)	New Instructions (Blue Carton)
<b>Eye Protection</b>	None	Added step 1 to: "Put on eye protection" before mixing
<b>Initial Fill Volume</b>	7.7 Liters	7.5 Liters
<b>Mixing Water Temp.</b>	24° C +/- 2°C	20°C and 30°C (68°F and 86°F)
<b>Mixing</b>	Gently agitate to dissolve powder	Cap and gently agitate until the powder is completely dissolved.
<b>Visually inspect the fluid</b>	None	After mixing, wait 2 minutes, then verify the solution is clear and no powder remains
<b>What to do if the solution is still cloudy and powder remains</b>	None	Repeat steps 6 and 8
<b>Labeling</b>	None	Label the container with the date and time of mixing

**Changes to the storage instructions include:**

- New storage temperature range
- New temperature exposure duration

	Old Instructions (Pink Pkg)	New Packaging (Blue Pkg)
<b>Storage Temperature</b>	Protect from excessive heat and freezing	Provides a storage temperature range: 5°C and 30°C (41°F and 80°F)
<b>Temperature Exposure</b>	None	Provides a temperature Exposure range: 0°C and up to 40°C (32°F and 104°F) for a period of 72 hours

**What has NOT changed:**

- Catalog numbers remain
  - > 08-4110-6 for Rx-10
  - > 08-4400-1 for Bicarbonate Carton
  - > Product yields remain unchanged

▶ Please familiarize yourself with the changes and how these may impact your storage and preparation of the product.

If in need of further assistance, please contact Technical Services at **1-800-227-2572**. Thank you for your continued support of Fresenius Medical Care North America.

Sincerely,

Stephen Jaquith

Product Director, Concentrates and Dialyzers  
Fresenius Medical Care Renal Technologies