



NaturalLyte® DRY PACK FOR BICARBONATE DIALYSIS

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 dialysate 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. Do not combine solutions from different batches. Bacterial growth can occur when using bicarbonate concentrate.
- Container must be free of bacterial and chemical contamination per ISO 23500. Use of a contaminated container to mix concentrate may result in patient injury or death.

Ionic Contribution of Bicarbonate Concentrate:
(Nominal dilution 1:1.72:42.28,
Acid to Bicarbonate to Water)
SODIUM BICARBONATE 37mEq/L
Chemical Composition of Bicarbonate Concentrate:
650 g Sodium Bicarbonate, USP/Ph. Eur.
Dissolved 81.25 g/L

CAUTION

- Federal law (U.S.A.) 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 8.0 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.

FRESENIUS MEDICAL CARE
RENAL THERAPIES GROUP

Manufacturer:
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NaturalLyte® DRY PACK FOR BICARBONATE DIALYSIS

Catalog No. **08-4400-1**

45X
B' CONCENTRATE
Dry Pack For
Bicarbonate Hemodialysis



PUSH UP HERE
PUSH UP HERE
TO OPEN

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.



DIRECTIONS FOR USE
One NaturalLyte Dry Pack will produce **8 liters** of bicarbonate concentrate for a treatment of approximately 7 hours at a maximum flow rate of 500 mL/min.

1. Put on eye protection.
2. Gather a mixing container and cap.
3. Add approximately 7.5 liters of purified water (ISO 13959 or AAMI RD62 quality) to the container.
4. Add the entire contents of the NaturalLyte Dry Pack to the container.

NOTE: If any powder spills outside the container, discard the carton and re-start the procedure using a new carton and a clean mixing container.

5. Cap and agitate the container until the powder is **completely dissolved**.

NOTE: Agitating the container several minutes may be needed.

6. Add purified water to bring the total volume to 8.0 liters. Replace the cap securely, and gently agitate the container 4-5 times.
7. Let the container stand for 2 minutes then slowly loosen and remove the cap. Visually inspect the solution to verify the solution is clear and that no powder remains on the bottom of the container.
8. If solution is cloudy or powder remains, agitate the container until the powder is completely dissolved, then repeat step 7.

NOTE: Do not continue to mix once the powder is completely dissolved.

9. Label the container with the date and time of mixing.

NOTE: Refer to the directions for use provided in the dialysis machine operator's manual to ensure proper setup.

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45X
B' CONCENTRATE
Dry Pack For
Bicarbonate Hemodialysis



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

REQUIREMENTS

- For use only with three-stream proportioning hemodialysis machines when calibrated to proportion 1-part acid to 1.72 parts bicarbonate to 42.28 parts water that meets the requirements of ISO 13959 or AAMI RD62
- Use only with 45x acid ('A') concentrates



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