



Stand the bag upright

Shake the bag gently to clear contents from top

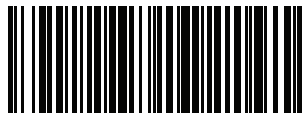
Carefully cut the bag open diagonally across one corner

Carefully pour the contents into the mixer as instructed by this product label

NaturaLyte[®] Dry Bicarbonate Concentrate For Bicarbonate Hemodialysis

Catalog No.

08-4112-2



Rx - 12

96 LITER MIX (25.36 GALLONS)

45X

'B' CONCENTRATE

Bicarbonate Concentrate Chemical Composition

SODIUM BICARBONATE USP 7807 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 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. 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 (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 96 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 RD62 water quality requirements.
- For use only with 45x acid ('A') concentrates.

DIRECTIONS FOR USE

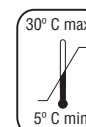
One bag of NaturaLyte Rx-12 will produce enough bicarbonate concentrate for approximately twelve 7 hour treatments at a maximum flow rate of 500 mL/min.

One bag of NaturaLyte Rx-12, when mixed according to directions, produces 96 liters of bicarbonate concentrate.

- 1) To mix NaturaLyte Rx-12 dry pack, add 90 liters of purified water to a mixer or container with at least 100 liters capacity. Use purified water that meets ISO 13959 or AAMI RD62 quality requirements.
- 2) Empty the entire NaturaLyte Rx-12 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 96 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 CO₂ 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.



Patents apply, visit www.fmcna.com/patents

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