

NATURALYTE®

Liquid Acid Concentrate For
Bicarbonate Hemodialysis

45X

'A' CONCENTRATE

3.43 LITERS (0.9 GALLONS)

1.0 K

3.0 Ca

Catalog No.
08-1301-4

INDICATIONS FOR USE

NATURALYTE Liquid Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. NATURALYTE Liquid Acid 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.

WARNING

- Failure to follow these Instructions for Use may result in 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. Refer to hemodialysis machine manufacturer's instructions to determine conductivity and pH of final dialysate.
- This product contains acetic acid and yields 4 mEq/L of acetate in the final dialysate. Following diffusion from the dialysate across the dialysis membrane to the blood, acetate is metabolized to bicarbonate. While the acetate from the acid concentrate will contribute to the serum bicarbonate level, the serum bicarbonate level of the patient during and immediately after the dialysis treatment is principally determined by the prescribed bicarbonate concentration which is set on the hemodialysis machine. Prescription of insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Wear safety glasses, gloves and clothing suitable to prevent exposure when handling. Acid concentrate can irritate eyes and skin.
- Do not use if package is damaged or seal is broken.

Patents apply, visit www.fmcna.com/patents

Nominal
Ionic
Contribution
to Dialysate

Nominal
Final
Dialysate
Composition

SODIUM
POTASSIUM
CALCIUM
MAGNESIUM
ACETATE
CHLORIDE
DEXTROSE
BICARBONATE*

100 mEq/L
1.0 mEq/L
3.0 mEq/L
1.0 mEq/L
4.0 mEq/L
105.0 mEq/L
100 mg/dL
N/A

137 mEq/L
1.0 mEq/L
3.0 mEq/L
1.0 mEq/L
4.0 mEq/L
105.0 mEq/L
100 mg/dL
33 mEq/L

*Post reaction Bicarbonate

Nominal Chemical Composition

263 g/L NaCl, 3.35 g/L KCl, 7.49 g/L CaCl₂,
2.14 g/L MgCl₂, 10.8 g/L CH₃CO₂H, 45.0 g/L Dextrose

REQUIREMENTS

For use only with a three-stream hemodialysis machine 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. Use only with 45X bicarbonate ('B') concentrates.

STORAGE AND DISPOSAL

Store 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 of up to 72 hours. Mix thoroughly before use. Keep container sealed when not in use. Dispose of unused concentrate in accordance with local, state, and federal regulations.



**FRESENIUS
MEDICAL CARE**

RENAL THERAPIES GROUP



Manufacturer:
Fresenius Medical Care
Renal Therapies Group, LLC
Waltham, MA 02451 U.S.A.
1-800-323-5188



08-1301-4



Exp. Date:

LOT