

NATURALYTE®

Liquid Acid Concentrate For Bicarbonate Hemodialysis



208.2 liters (55 gallons)

1.0 K

2.5 Ca

Catalog No.
13-1251-1

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 the eyes and skin.
- Do not use if package is damaged or seal is broken.

Nominal Chemical Composition	Liquid Acid Contribution to Final Dialysate: 1:44 (Nominal Dilution)	Nominal Chemical Composition of Final Dialysate: Acid:Bicarbonate:Water (1:1.72:42.28)
NaCl 263 g/L	SODIUM 100 mEq/L	SODIUM 137 mEq/L
KCl 3.35 g/L	POTASSIUM 1.0 mEq/L	POTASSIUM 1.0 mEq/L
CaCl₂ 6.24 g/L	CALCIUM 2.5 mEq/L	CALCIUM 2.5 mEq/L
MgCl₂ 2.14 g/L	MAGNESIUM 1.0 mEq/L	MAGNESIUM 1.0 mEq/L
CH₃CO₂H 10.8 g/L	ACETATE 4.0 mEq/L	ACETATE 4.0 mEq/L
C₆H₁₂O₆ 45.0 g/L	CHLORIDE 104.5 mEq/L	CHLORIDE 104.5 mEq/L
	DEXTROSE 100 mg/dL	DEXTROSE 100 mg/dL
		BICARBONATE** 33 mEq/L

** Post reaction Bicarbonate

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**

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Exp. Date: