

3.0 K**WARNING:** For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. NOT FOR PARENTERAL USE.**2.0 Ca****45x**

Naturalyte®

Acid Concentrate for Bicarbonate Dialysis

3.43 Liters**08-3201-4****Ionic Contribution of Acid Concentrate (Nominal Dilution 1:44)**

SODIUM	100	mEq/L
POTASSIUM	3.0	
CALCIUM	2.0	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	106.00	
DEXTROSE	100	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263 g	MgCl ₂	2.14 g
KCl	10.1 g	CH ₃ CO ₂ H	10.8 g
CaCl ₂	4.99 g	C ₆ H ₁₂ O ₆	45.0 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L, chloride 106.00 mEq/L, and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION: Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

WARNING: This acid concentrate product is for use as one component in mixing dialysate bath. This product contains acetic acid and, after mixing, yields 4 milliequivalents per liter of acetate in the dialysate. After diffusion across the dialyzer membrane, acetate is metabolized by the liver to serum bicarbonate and adds to the serum bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the dynamic of diffusion and concentration gradients prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration. The bicarbonate concentration of the dialysate is the bicarbonate setting on the dialysis machine, and is the bicarbonate dose prescribed by the physician. On Fresenius 2008 series hemodialysis machines, the bicarbonate dose may be set in a range between 20 and 40 milliequivalents per liter, but may be set in different ranges in other machines.

When the dialysis session terminates, acetate that has not yet metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion ceases, without possibility of diffusion out of the blood. The post dialysis metabolism of acetate could thus briefly increase serum bicarbonate concentration above the prescribed bicarbonate concentration of the dialysate. Physicians should consider this possibility in prescribing bicarbonate dose.

Prescription of insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes, including increased mortality risk.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

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

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EXPIRATION
DATE:

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	Customer Fresenius Medical Care	Colors PMS 192 Red PMS 246 Purple PMS Black Die Line (Does Not Print)	Label Specs/Finishing Info Label Size 4.00" x 5.00" Roll Size 2300 / ROLL Unwind Position Out Bottom / 2 Stock White Semi Gloss w/Permanent Adhesive	Disclaimer Please check this proof carefully for errors, color correctness, color split, and label specifications, and indicate any corrections, changes or additions needed. We cannot be responsible for errors, corrections and/or changes that are not marked on this proof and/or submitted through Approvallink.com. <input type="checkbox"/> This proof is approved... <input type="checkbox"/> as is <input type="checkbox"/> as corrected <input type="checkbox"/> Submit new proof with corrections indicated
	Product Number 71-4321	Notes Rev4 - Reduced height of purple and red bars, changed copy, changed left column layout.		
	Description 3201 Bottle Label			
	Revision 4.0			
	Date 4/17/15			

Signature _____ Date _____