3.0 K GRANUFLO® 3.0 Ca

NaturaLyte® Dry Acid Concentrate For Bicarbonate Dialysis

45x

62.5 LITER MIX (16.5 GAL)

NON-PYROGENIC

WARNING: Acid concentrate is formulated to be used in a three-stream hemodialysis machine calibrated to an acid concentrate dilution of 1:44. Use with other equipment may result in patient injury. NOT FOR PARENTERAL USE. For use only with NaturaLyte® 4000 Series Bicarbonate or equivalent (refer to label). **Use of this Acid Concentrate without associated bicarbonate concentrate may cause patient injury or death. Check conductivity and pH of dialysate just prior to dialysis treatment and each time new concentrate is supplied to the machine.**

WARNING: This acid concentrate product is for use as one component in mixing dialysate bath. This product contains sodium diacetate and, after mixing, yields 8 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.

IONIC CONTRIBUTION OF ACID CONCENTRATE: (Nominal Dilution 1:44)

SODIUM	100 mEq/L
POTASSIUM	3.0 mEq/L
CALCIUM	3.0 mEq/L
MAGNESIUM	1.0 mEq/L
ACETATE	8.0 mEq/L
CHLORIDE	103.00 mEq/L
DEXTROSE	100 mg/dL

CHEMICAL COMPOSITION

Total

22.0 kg

NaCl	15.8 kg
KCl	0.629 kg
$CaCl_2*2H_2O$	0.620 kg
$MgCl_2*6H_2O$	0.286 kg
$CH_3COONa–CH_3COOH$	1.60 kg
$C_6H_{12}O_6•H_2O$	3.09 kg

DILUTION INSTRUCTIONS

(The contents may clump or harden which does not affect product chemical composition)

1) **Use water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards.** Water temperature should be 20°– 30° C to optimize dissolving.
2) Add approximately 10 gallons of water to mixing container. Water and feed line must be free of bacterial and chemical contamination (ANSI/AAMI).
   IMPORTANT:
3) Use entire contents of each bag (3) within this box. Do not use unless all (3) bags are present. The contents of the bags are different. All bags must be used.
   NOTE: Refer to Dissolution System Operator's Manual. Label tank with contents and date prepared.
4) Add additional water to dissolution tank final fill level.
5) Fully dissolved, this will make 62.5 liters (16.5 gal) of solution. Eight (8) cases of identical chemical composition produce 500 liters (132 gal). Six (6) cases make 375 liters (99 gal).
6) Mix solution until completely dissolved. Filter with 1.2 micron filter or finer before use. Keep container sealed. Label and date all storage containers.

CAUTION: Refer to instructions provided by the hemodialysis machine manufacturer.
Federal law (USA) restricts this device to sale by or on order of a physician.
AVOID EXCESSIVE TEMPERATURE. PROTECT FROM MOISTURE.
DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.

FRESENIUS MEDICAL CARE

Fresenius Medical Care
Renal Therapies Group, LLC
Waltham, MA 02451
1-800-323-5188

Cat. No. 0FD3301-3B

Printed in USA 71-4310.03 08/14