GRANUFLO®

Dry Acid Concentrate For Bicarbonate Hemodialysis

Catalog No.

0FD2231-3B

2.0 K **2.25 Ca**

45X
'A' CONCENTRATE

INDICATIONS FOR USE

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

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.

⚠ 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. 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.
- This product contains sodium diacetate and yields 8 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 any bag is open or damaged. Do not use unless all 3 bags are present.

	Nominal Ionic Contribution to Dialysate	Nominal Final Dialysate Composition
SODIUM	100 mEq/L	137 mEq/L
POTASSIUM	2.0 mEq/L	2.0 mEq/L
CALCIUM	2.25 mEq/L	2.25 mEq/L
MAGNESIUM	1.0 mEq/L	1.0 mEq/L
ACETATE	8.0 mEq/L	8.0 mEq/L
CHLORIDE	101.25 mEq/L	101.25 mEq/L
DEXTROSE	100 mg/dL	100 mg/dL
BICARBONATE*	N/A	33 mEq/L

*Post Reaction Bicarbonate

Nominal Chemical Composition of GRANUFLO Case

15.8 kg NaCl, 0.419 kg KCl, 1.60 kg $NaH(OAc)_2$,
0.286 kg $MgCl_2 \bullet 6H_2O$, 0.465 kg $CaCl_2 \bullet 2H_2O$,
3.09 kg Dextrose$\bullet H_2O$ (Net. Wt. 21.7 kg)

DIRECTIONS FOR MIXING

GRANUFLO must be mixed in Fresenius Dissolution Units with ISO 13959 or AAMI RD62 quality water. Add six cases of GRANUFLO to a 99 gallon Dissolution Unit or eight cases to a 132 gallon Dissolution Unit. Use entire contents of each bag (3) in this case. One case of GRANUFLO produces 62.5 liters (16.5 gallons) of liquid concentrate. Refer to the Dissolution Unit Operator's Manual for detailed mixing instructions.

NOTE: GRANUFLO Dry Acid Concentrate may compact or clump during handling and storage. Break clumps prior to mixing. Compacting or clumping does not affect chemical composition.

STORAGE AND DISPOSAL:

Store in a dry location between 5ºC and 30ºC (41ºF and 86ºF). Product can withstand an exposure to temperatures down to 0ºC and up to 40ºC (32ºF to 104ºF) for a period of up to 72 hrs. Dispose of unused concentrate in accordance with local, state and federal regulations.

Patents apply, visit www.fmcna.com/patents

Exp. Date:

0FD2231-3B

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RENAL THERAPIES GROUP

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