

3.0 K**WARNING:** NOT FOR PARENTERAL USE. Use of this Acid Concentrate without the associated Bicarbonate Concentrate may cause patient injury or death.**2.5 Ca****45X**

CITRASATE®

Acid Concentrate Liquid for Bicarbonate Dialysis

55 gallons (208.2 liters)**13-3251-CA****Dialysate Concentration**Not including bicarbonate concentrate
(Nominal Dilution 1:44)

SODIUM	100.3 mEq/L
POTASSIUM	3.0 mEq/L
CALCIUM	2.5 mEq/L
MAGNESIUM	1.0 mEq/L
CITRATE	2.4 mEq/L
ACETATE	0.3 mEq/L
CHLORIDE	106.5 mEq/L
DEXTROSE	100 mg/dL

Chemical CompositionAcid Concentrate (gram/Liter)
(pre-dilution)

NaCl	263 g/L
KCl	10.1 g/L
CaCl₂	6.24 g/L
MgCl₂	2.14 g/L
C₆H₈O₇	6.92 g/L
NaC₂H₃O₂	1.11 g/L
C₆H₁₂O₆	45.0 g/L

NON-PYROGENIC**AVOID EXCESSIVE HEAT AND PROTECT FROM FREEZING**

Description for Use: For use with FMCNA 45X sodium bicarbonate with a three-stream hemodialysis machine set for 45X. Use only with purified water that meets ANSI/AAMI RD62 or ISO 13959 standards for dialysis water. When 1 part acid concentrate is mixed with 1.72 parts of bicarbonate concentrate and 42.28 parts purified water, the final ionic contribution in the Final Dialysate is: Sodium 137 mEq/L and Bicarbonate* 34.6 mEq/L (*pre-reaction bicarbonate: 37 mEq/L). All other constituents remain unchanged.

CAUTION: Refer to instructions provided by the hemodialysis machine manufacturer. **Check conductivity and pH of final dialysate just prior to dialysis treatment and each time new concentrate is supplied to the machine.** Refer to manufacturer for nominal conductivity of final dialysate. Use only as directed. Mix thoroughly before use. Keep container sealed when not in use. Federal law (USA) restricts this device to sale by or on the order of a physician.

Do not use if seals or containers are damaged.

WARNING: This acid concentrate product is for use as one component in mixing dialysate bath. This product contains sodium acetate and citric acid and, after mixing, yields 0.3 milliequivalents per liter of acetate and 2.4 milliequivalents per liter of citrate in the dialysate. After diffusion across the dialyzer membrane, acetate and citrate are 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 and citrate that have 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 and citrate 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.

Citrasate® is a registered trademark of Advanced Renal Technologies.
U.S. Patent 6,610,206 and others applied for.

MANUFACTURER/DISTRIBUTOR:

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