

## PRODUCT INFORMATION NOTICE







November 27, 2018

Dear Valued Customer:

The purpose of this notification is to make you aware of updates to all liquid and dry acid concentrate labels manufactured by Fresenius Medical Care Renal Technologies.

### Updates that apply to all labels include:

- **Color** – Each brand of acid will be identified by a color branding scheme that will apply to the header and border of the label, for example NaturaLyte® labels will be purple, Citrasate® liquid will be identified by yellow, Granuflo® will be identified by red and lastly Citrasate Dry will be identified by yellow and black.
- **Indication for Use** – An indications statement has been added to all concentrate labels
- **Potassium & Calcium Values** – Location and visual appearance of the Potassium (K) and Calcium (Ca) values has been changed.
  - **Potassium** will be identified by black letters on a white background outlined in red **1.0 K**
  - **Calcium** will be identified by white letters on a red background **2.5 Ca**
- **Icons** – Several visual icons have been added to the label to indicate:

	Warning or Caution
	Lot Number
	Expiration Date
	Manufacturer
	Storage Temperature Range
	Store in a dry location (GranuFlo & Citrasate Dry)

- **Nominal Final Dialysate Composition** – Composition of all constituents in the final dialysate at nominal values, including post reaction bicarbonate

	Nominal Ionic Contribution to Dialysate	Nominal Final Dialysate Composition
<b>SODIUM</b>	100 mEq/L	137 mEq/L
<b>POTASSIUM</b>	2.0 mEq/L	2.0 mEq/L
<b>CALCIUM</b>	2.5 mEq/L	2.5 mEq/L
<b>MAGNESIUM</b>	1.0 mEq/L	1.0 mEq/L
<b>ACETATE</b>	8.0 mEq/L	8.0 mEq/L
<b>CHLORIDE</b>	101.5 mEq/L	101.5 mEq/L
<b>DEXTRROSE</b>	100 mg/dL	100 mg/dL
<b>BICARBONATE*</b>	N/A	33 mEq/L

\* Post Reaction Bicarbonate

- Storage Instructions, **new storage temperature range** and **storage temperature exposure** duration.

	Old Packaging	New Packaging
Storage Temperature	Protect from excessive heat and freezing	<b>Provides a storage temperature range: 5°C and 30°C (41°F and 86°F)</b>
Temperature Exposure	None	<b>Provides a temperature Exposure range: 0°C and up to 40°C (32°F and 104°F) for a period of 72 hours</b>

The following pages represent side by side examples of the old vs. the new, updated labels for all acid concentrate brand/ packaging configurations. Please review the layout and locations of key fields, such as:

- Catalog Number
- Potassium Value
- Calcium Value
- Indications for Use
- Nominal Ionic Contribution to Dialysate
- Nominal Final Dialysate Composition
- Requirements
- Warnings and Cautions
- Chemical Composition
- Storage and Disposal

# Label Examples:

## Old NaturaLyte Bottle

**1.0 K** **2.5 Ca**

**45x** **NaturaLyte** **08-1251-1**

**Acid Concentrate for Bicarbonate Dialysis**

**3.43 Liters**

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

SODIUM	100 mEq/L
POTASSIUM	1.0 mEq/L
CALCIUM	2.5 mEq/L
MAGNESIUM	1.0 mEq/L
ACETATE	4.0 mEq/L
CHLORIDE	104.5 mEq/L
DEXTROSE	100 mg/dL

**CHEMICAL COMPOSITION Acid Concentrate (gm/L)**

NaCl	263 g	MgCl <sub>2</sub>	2.14 g
KCl	3.35 g	CH <sub>3</sub> CO <sub>2</sub> H	10.8 g
CaCl <sub>2</sub>	6.24 g	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	45.0 g

**NON-PYROGENIC**

**INDICATIONS FOR USE**

**WARNING**

**CAUTION**

**PRESCRIPTION INFORMATION**

**LOT NO.**

**EXPIRATION DATE:**

Printed in U.S.A. 71-4331-05 04/15

## New NaturaLyte Bottle

**NATURALYTE** **Liquid Acid Concentrate For Bicarbonate Hemodialysis** **45x**

**3.43 LITERS (9.09 GALLONS)**

**1.0 K 2.5 Ca** **Catalog No. 08-1251-1**

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

SODIUM	100 mEq/L	SODIUM	137 mEq/L
POTASSIUM	1.0 mEq/L	POTASSIUM	1.0 mEq/L
CALCIUM	2.5 mEq/L	CALCIUM	2.5 mEq/L
MAGNESIUM	1.0 mEq/L	MAGNESIUM	1.0 mEq/L
ACETATE	4.0 mEq/L	ACETATE	4.0 mEq/L
CHLORIDE	104.5 mEq/L	CHLORIDE	104.5 mEq/L
DEXTROSE	100 mg/dL	DEXTROSE	100 mg/dL
BICARBONATE*	N/A	BICARBONATE*	33 mEq/L

**INDICATIONS FOR USE**

**WARNING**

**CAUTION**

**PRESCRIPTION INFORMATION**

**LOT**

Printed in USA R0000115.03 09/18

## Old NaturaLyte Drum

**1.0 K** **2.5 Ca**

**45x** **NaturaLyte** **1251**

**4000 Series Acid Concentrate for Bicarbonate Dialysis** **208.2 Liters (55 Gallons)**

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

SODIUM	100 mEq/L
POTASSIUM	1.0 mEq/L
CALCIUM	2.5 mEq/L
MAGNESIUM	1.0 mEq/L
ACETATE	4.0 mEq/L
CHLORIDE	104.5 mEq/L
DEXTROSE	100 mg/dL

**CHEMICAL COMPOSITION Acid Concentrate (gm/L)**

NaCl	263 g	MgCl <sub>2</sub>	2.14 g
KCl	3.35 g	CH <sub>3</sub> CO <sub>2</sub> H	10.8 g
CaCl <sub>2</sub>	6.24 g	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	45.0 g

**NON-PYROGENIC**

**INDICATIONS FOR USE**

**WARNING**

**CAUTION**

**PRESCRIPTION INFORMATION**

**LOT NO.**

**EXPIRATION DATE:**

**CAT. NO. 13-1251-1**

Printed in U.S.A. 71-4553-05 09/14

## New NaturaLyte Drum

**NATURALYTE** **Liquid Acid Concentrate For Bicarbonate Hemodialysis** **45x**

**208.2 Liters (55 Gallons)**

**1.0 K 2.5 Ca** **Catalog No. 13-1251-1**

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

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
CaCl <sub>2</sub>	6.24 g/L	CALCIUM	2.5 mEq/L	CALCIUM	2.5 mEq/L
MgCl <sub>2</sub>	2.14 g/L	MAGNESIUM	1.0 mEq/L	MAGNESIUM	1.0 mEq/L
CH <sub>3</sub> CO <sub>2</sub> H	10.8 g/L	ACETATE	4.0 mEq/L	ACETATE	4.0 mEq/L
C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	45.0 g/L	CHLORIDE	104.5 mEq/L	CHLORIDE	104.5 mEq/L
		DEXTROSE	100 mg/dL	DEXTROSE	100 mg/dL
		BICARBONATE*	N/A	BICARBONATE*	33 mEq/L

**INDICATIONS FOR USE**

**WARNING**

**CAUTION**

**PRESCRIPTION INFORMATION**

**LOT**

Printed in USA R0000430.03 09/18

Label Examples:

Old Citrasate Bottle

**1.0 K 2.5 Ca** **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®** 1-gallon (3.785 liters)  
**08-1251-CA**  
Acid Concentrate Liquid for Bicarbonate Dialysis

**Dialysate Concentration**  
Not including bicarbonate concentrate  
(Nominal Dilution 1:44)

SODIUM	100.3 mEq/L
POTASSIUM	1.0 mEq/L
CALCIUM	2.5 mEq/L
MAGNESIUM	1.0 mEq/L
CITRATE	2.4 mEq/L
ACETATE	0.3 mEq/L
CHLORIDE	104.5 mEq/L
DEXTROSE	100 mg/dL

**Chemical Composition**  
Acid Concentrate (gram/Liter)  
(nominal dilution)

NaCl	263 g/L
KCl	3.35 g/L
CaCl <sub>2</sub>	3.24 g/L
MgCl <sub>2</sub>	2.14 g/L
C <sub>6</sub> H <sub>5</sub> O <sub>7</sub>	6.92 g/L
NaC <sub>2</sub> H <sub>3</sub> O <sub>2</sub>	1.11 g/L
C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	45.0 g/L

**NON-PYROGENIC**  
**AVOID EXCESSIVE HEAT AND PROTECT FROM FREEZING**  
Description for Use: For use with F802A 45X sodium bicarbonate sets in three-stream hemodialysis machine set for 45X. Use only with purified water that meets AAMI/ANSI R052 or ISO 13959 standards for dialysis water. When 1 part acid concentrate is mixed with 1.72 parts of bicarbonate concentrate and 0.23 parts purified water the final ionic contribution in the final dialysate is: Sodium 117 mEq/L and bicarbonate 34.8 mEq/L (non-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 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.

**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 mEq/L of citrate and 0.3 mEq/L of acetate per liter of dialysate. The dialysate bath is intended for use in the dialyzer. After diffusion across the dialyzer membrane, acetate and citrate are metabolized by the liver to serum bicarbonate and enter the liver stream bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the patient's acetate and citrate concentrations gradually prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration, and as the bicarbonate dose prescribed by the physician. On treatment with 45X series hemodialysis machines, the bicarbonate dose may be set in a range between 30 and 45 mEq/L per liter. This acid concentrate may be set in a different range in other machines. When the dialysis session terminates, acetate and citrate that have not yet been metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion across, without possibility of diffusion out of the blood. The post-dialysis metabolism of acetate and citrate could then further 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.

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**MANUFACTURER/DISTRIBUTOR:**  
Fresenius Medical Care  
Renal Therapies Group, LLC  
Waltham, MA 02451  
1-800-323-5188

**FRESENIUS MEDICAL CARE**

LOT NO. EXPIRATION DATE: **08-1251-CA**  
Printed in U.S.A. 71-0302-00 08/15

New Citrasate Bottle

**CITRASATE®** Liquid Acid Concentrate For Bicarbonate Hemodialysis **45X**  
**3.785 LITERS (1 GALLON)**

**1.0 K 2.5 Ca** Catalog No. **08-1251-CA**

**INDICATIONS FOR USE**  
CITRASATE Liquid Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. CITRASATE 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 citric acid and sodium acetate and yields 2.4 mEq/L of citrate and 0.3 mEq/L of acetate in the final dialysate. Following diffusion from the dialysate across the dialysis membrane to the blood, citrate and acetate are 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 (USA) 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 package is damaged or seal is broken.  
Patents apply. visit [www.fmc.com/patents](http://www.fmc.com/patents)

Nominal Ionic Contribution to Dialysate	Nominal Final Dialysate Composition	
SODIUM	100.3 mEq/L	137.3 mEq/L
POTASSIUM	1.0 mEq/L	1.0 mEq/L
CALCIUM	2.5 mEq/L	2.5 mEq/L
MAGNESIUM	1.0 mEq/L	1.0 mEq/L
ACETATE	0.3 mEq/L	0.3 mEq/L
CITRATE	2.4 mEq/L	2.4 mEq/L
CHLORIDE	104.5 mEq/L	104.5 mEq/L
DEXTROSE	100 mg/dL	100 mg/dL
BICARBONATE*	N/A	34.8 mEq/L

\* Post reaction Bicarbonate

**Nominal Chemical Composition**  
263 g/L NaCl, 3.35 g/L KCl, 45.0 g/L Dextrose, 1.11 g/L NaOAc, 2.14 g/L MgCl<sub>2</sub>, 6.24 g/L CaCl<sub>2</sub>, 6.92 g/L C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>

**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 R052 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**  
RENAL THERAPIES GROUP

**MANUFACTURER:**  
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1-800-323-5188

LOT NO. EXPIRATION DATE: **08-1251-CA**  
Printed in USA R000077.03 09/18

Old Citrasate Drum

**1.0 K 2.5 Ca** **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®** 55 gallons (208 liters)  
**13-1251-CA**  
Acid Concentrate Liquid for Bicarbonate Dialysis

**Dialysate Concentration**  
Not including bicarbonate concentrate  
(Nominal Dilution 1:44)

SODIUM	100.3 mEq/L
POTASSIUM	1.0 mEq/L
CALCIUM	2.5 mEq/L
MAGNESIUM	1.0 mEq/L
CITRATE	2.4 mEq/L
ACETATE	0.3 mEq/L
CHLORIDE	104.5 mEq/L
DEXTROSE	100 mg/L

**Chemical Composition**  
Acid Concentrate (gram/Liter)  
(nominal dilution)

NaCl	263.00 g/L
KCl	3.35 g/L
CaCl <sub>2</sub>	6.24 g/L
MgCl <sub>2</sub>	2.14 g/L
C <sub>6</sub> H <sub>5</sub> O <sub>7</sub>	6.92 g/L
NaC <sub>2</sub> H <sub>3</sub> O <sub>2</sub>	1.11 g/L
C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	45.00 g/L

**NON-PYROGENIC**  
**AVOID EXCESSIVE HEAT AND PROTECT FROM FREEZING**  
Description for Use: For use with F802A 45X sodium bicarbonate sets in three-stream hemodialysis machine set for 45X. Use only with purified water that meets AAMI/ANSI R052 or ISO 13959 standards for dialysis water. When 1 part acid concentrate is mixed with 1.72 parts of bicarbonate concentrate and 0.23 parts purified water the final ionic contribution in the final dialysate is: Sodium 117 mEq/L and bicarbonate 34.8 mEq/L (non-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 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.

**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 mEq/L of citrate and 0.3 mEq/L of acetate per liter of dialysate. The dialysate bath is intended for use in the dialyzer. After diffusion across the dialyzer membrane, acetate and citrate are metabolized by the liver to serum bicarbonate and enter the liver stream bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the patient's acetate and citrate concentrations gradually prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration, and as the bicarbonate dose prescribed by the physician. On treatment with 45X series hemodialysis machines, the bicarbonate dose may be set in a range between 30 and 45 mEq/L per liter. This acid concentrate may be set in a different range in other machines. When the dialysis session terminates, acetate and citrate that have not yet been metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion across, without possibility of diffusion out of the blood. The post-dialysis metabolism of acetate and citrate could then further 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.

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**FRESENIUS MEDICAL CARE**

LOT NO. EXPIRATION DATE: **13-1251-CA**  
Printed in U.S.A. 71-0302-00 08/15

New Citrasate Drum

**CITRASATE®** Liquid Acid Concentrate For Bicarbonate Hemodialysis **45X**  
**208.2 Liters (55 gallons)**

**1.0 K 2.5 Ca** Catalog No. **13-1251-CA**

**INDICATIONS FOR USE**  
CITRASATE Liquid Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. CITRASATE 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 citric acid and sodium acetate and yields 2.4 mEq/L of citrate and 0.3 mEq/L of acetate in the final dialysate. Following diffusion from the dialysate across the dialysis membrane to the blood, citrate and acetate are 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 (USA) 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 package is damaged or seal is broken.  
Patents apply. visit [www.fmc.com/patents](http://www.fmc.com/patents)

Nominal Chemical Composition	Liquid Acid Contribution to Final Dialysate (as Bicarbonate)	Nominal Chemical Composition of Final Dialysate (as Bicarbonate)
NaCl	263.00 g/L	137.3 mEq/L
KCl	3.35 g/L	1.0 mEq/L
CaCl <sub>2</sub>	6.24 g/L	2.5 mEq/L
MgCl <sub>2</sub>	2.14 g/L	1.0 mEq/L
C <sub>6</sub> H <sub>5</sub> O <sub>7</sub>	6.92 g/L	0.3 mEq/L
NaC <sub>2</sub> H <sub>3</sub> O <sub>2</sub>	1.11 g/L	0.3 mEq/L
C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	45.00 g/L	104.5 mEq/L
DEXTROSE	100 mg/L	100 mg/dL
BICARBONATE*	N/A	34.8 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 R052 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**  
RENAL THERAPIES GROUP

**MANUFACTURER:**  
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Renal Therapies Group, LLC  
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1-800-323-5188

LOT NO. EXPIRATION DATE: **13-1251-CA**  
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# Label Examples:

## Old Citrasate Dry

**1.0 K**
**2.5 Ca**

**Citrasate Dry**  
Dry Acid Concentrate For Bicarbonate Dialysis

**NON-PYROGENIC**

Chemical Contents of Dry Acid Concentrate (A):	Ionic Contribution of Liquid Acid Concentrate (A):	45X Final Dialysate Nominal Ionic Concentrations:
<b>NaCl</b> 18.44 kg	<b>SODIUM</b> 100.3 mEq/L	<b>SODIUM</b> 137.3 mEq/L
<b>KCl</b> 0.219 kg	<b>POTASSIUM</b> 1.0 mEq/L	<b>POTASSIUM</b> 1.0 mEq/L
<b>CaCl<sub>2</sub> • 2H<sub>2</sub>O</b> 0.517 kg	<b>CALCIUM</b> 2.5 mEq/L	<b>CALCIUM</b> 2.5 mEq/L
<b>MgCl<sub>2</sub> • 6H<sub>2</sub>O</b> 0.286 kg	<b>MAGNESIUM</b> 1.0 mEq/L	<b>MAGNESIUM</b> 1.0 mEq/L
<b>C<sub>6</sub>H<sub>12</sub>O<sub>6</sub> • 2H<sub>2</sub>O</b> 0.115 kg	<b>ACETATE</b> 0.3 mEq/L	<b>ACETATE</b> 0.3 mEq/L
<b>C<sub>6</sub>H<sub>12</sub>O<sub>6</sub></b> 0.42 kg	<b>CITRATE</b> 2.4 mEq/L	<b>CITRATE</b> 2.4 mEq/L
<b>C<sub>6</sub>H<sub>12</sub>O<sub>6</sub> • H<sub>2</sub>O</b> 3.09 kg	<b>GLUCOSE</b> 100 mg/dL	<b>GLUCOSE</b> 100 mg/dL
<b>Total Wt:</b> 21.1 kg	<b>CHLORIDE</b> 104.5 mEq/L	<b>CHLORIDE</b> 104.5 mEq/L
	<b>BICARBONATE</b> 34.6 mEq/L	

**DESCRIPTION FOR USE:** For use with FMCNA 45X sodium bicarbonate with a three-stream hemodialysis machine set for 45X. This product is designed to be used in a closed system with a FMCNA Dry Acid Dissolution Unit.

**Non-pyrogenic Composition:** When 1 part acid concentrate is mixed with 172 parts of bicarbonate concentrate and 42.26 parts of purified water, the final concentration is 100 mg/dL glucose, 104.5 mEq/L chloride, and 34.6 mEq/L bicarbonate.

**CAUTION:** Refer to instructions provided by the hemodialysis machine manufacturer. Check conductivity and pH of final dialysate test prior to dialysis treatment and each time new concentrate is supplied to the machine. Do not use if package is open or damaged.

**WARNING:** This acid concentrate product is for use as one component in mixing dialysate. The product contains sodium acetate and citric acid and other strong acids. It is not intended for use as a dialysate. Other electrolytes in the dialysate, other electrolytes in the dialysate membrane, acetate and citrate are metabolized by the liver to form bicarbonate and water. The acetate and citrate are metabolized by the liver to form bicarbonate and water. The acetate and citrate are metabolized by the liver to form bicarbonate and water. The acetate and citrate are metabolized by the liver to form bicarbonate and water.

**INSTRUCTIONS FOR DISSOLUTION:** The contents may clump or harden which does not affect product chemical composition. Break clumps prior to mixing. When fully dissolved, six (6) cases produce 375 liters (99 gallons), eight (8) cases make 500 liters (132 gallons). Refer to FMCNA Dry Acid Dissolution Unit Operator's Manual for additional details.

- Use only with water that meets or exceeds ANSI/AAMI RD2 or ISO 19599 hemodialysis water quality standards. Water temperature should be 20°-30° C for proper dissolution.
- Perform a Rinse Cycle before starting the batch by pressing the Rinse Start button. Wait for cycle to complete before continuing.
- Begin the batch by pressing the Dissolution Start button. Wait until ADD GRANULES light begins to flash.
- Add Dry Acid to Dissolution Unit. Verify all cases are the same category. A formulation and lot # are printed on the bag. **IMPORTANT: Use expiry contents of each bag (3) within this case. Do not use unopened all (4) bags are present. The contents of the bags are different. All bags must be used. Label bag with contents and date prepared.**
- Continue with mixing procedure according to the FMCNA Dry Acid Dissolution Unit Operator's Manual.
- When mixing is complete, test for proper Specific Gravity according to the FMCNA Dry Acid Dissolution Unit Operator's Manual. Filter with a nominal 1 micron filter during transfer. Keep container sealed. Label and date all storage containers.

**AVOID EXCESSIVE TEMPERATURE. STORE IN A DRY LOCATION.**

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

**FMCNA Cat. No. OFD1251-DA**

Exp. Date  
Lot #

Printed in USA 71-4381-08/14

## New Citrasate Dry

**1.0 K**
**2.5 Ca**

**CITRASATE DRY**  
Dry Acid Concentrate For Bicarbonate Hemodialysis

**NON-PYROGENIC**

Nominal Ionic Contribution to Dialysate	Nominal Final Dialysate Composition
<b>SODIUM</b> 100.3 mEq/L	<b>SODIUM</b> 137.3 mEq/L
<b>POTASSIUM</b> 1.0 mEq/L	<b>POTASSIUM</b> 1.0 mEq/L
<b>CALCIUM</b> 2.5 mEq/L	<b>CALCIUM</b> 2.5 mEq/L
<b>MAGNESIUM</b> 1.0 mEq/L	<b>MAGNESIUM</b> 1.0 mEq/L
<b>ACETATE</b> 0.3 mEq/L	<b>ACETATE</b> 0.3 mEq/L
<b>CITRATE</b> 2.4 mEq/L	<b>CITRATE</b> 2.4 mEq/L
<b>CHLORIDE</b> 104.5 mEq/L	<b>CHLORIDE</b> 104.5 mEq/L
<b>GLUCOSE</b> 100 mg/dL	<b>GLUCOSE</b> 100 mg/dL
<b>BICARBONATE</b> 34.6 mEq/L	<b>BICARBONATE</b> 34.6 mEq/L

**INDICATIONS FOR USE:** CITRASATE DRY Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. CITRASATE 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 42.26 parts purified water that meets ISO 19599 or AAMI RD2 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.

**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 4 bags are present.

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

**MANUFACTURER:** Fresenius Medical Care Renal Therapies Group, LLC Waltham, MA 02451 U.S.A. 1-800-323-5188

## Old GranuFlo

**2.0 K**
**2.5 Ca**

**GRANUFLO**  
Dry Acid Concentrate For Bicarbonate Dialysis

**NON-PYROGENIC**

IONIC CONTRIBUTION OF ACID CONCENTRATE: (Nominal Dialysate 1.44)	Chemical Composition	Total
<b>SODIUM</b> 100 mEq/L	<b>NaCl</b>	<b>15.8 kg</b>
<b>POTASSIUM</b> 2.0 mEq/L	<b>KCl</b>	<b>0.419 kg</b>
<b>CALCIUM</b> 2.5 mEq/L	<b>CaCl<sub>2</sub> • 2H<sub>2</sub>O</b>	<b>0.517 kg</b>
<b>MAGNESIUM</b> 1.0 mEq/L	<b>MgCl<sub>2</sub> • 6H<sub>2</sub>O</b>	<b>0.286 kg</b>
<b>ACETATE</b> 8.0 mEq/L	<b>CH<sub>3</sub>COONa - CH<sub>3</sub>COOH</b>	<b>1.60 kg</b>
<b>CHLORIDE</b> 101.50 mEq/L	<b>CH<sub>3</sub>H<sub>2</sub>O - CH<sub>3</sub>COOH</b>	<b>3.09 kg</b>
<b>DEXTRIOSE</b> 100 mg/dL		

**DILUTION INSTRUCTIONS:** (The contents may clump or harden which does not affect product chemical composition) Use water that meets or exceeds ANSI/AAMI RD2 water quality standards. Water temperature should be 20°-30° C to optimize dissolving.

- Add approximately 10 gallons of water to mixing container. Water and feed line must be free of bacterial and chemical contamination (ANSI/AAMI).
- Use expiry contents of each bag (3) within this box. Do not use unopened (3) bags are present. The contents of the bags are different. All bags must be used. Label bag with contents and date prepared.
- 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).
- 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 (U.S.A.) restricts this device to sale by or on the order of a physician. **AVOID EXCESSIVE TEMPERATURE. PROTECT FROM MOISTURE. DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.**

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

**FMCNA Cat. No. OFD2251-3B**

Exp. Date

Printed in USA 900003-08 08/18

## New GranuFlo

**2.0 K**
**2.5 Ca**

**GRANUFLO**  
Dry Acid Concentrate For Bicarbonate Hemodialysis

**NON-PYROGENIC**

Nominal Ionic Contribution to Dialysate	Nominal Final Dialysate Composition
<b>SODIUM</b> 100 mEq/L	<b>SODIUM</b> 137 mEq/L
<b>POTASSIUM</b> 2.0 mEq/L	<b>POTASSIUM</b> 2.0 mEq/L
<b>CALCIUM</b> 2.5 mEq/L	<b>CALCIUM</b> 2.5 mEq/L
<b>MAGNESIUM</b> 1.0 mEq/L	<b>MAGNESIUM</b> 1.0 mEq/L
<b>ACETATE</b> 8.0 mEq/L	<b>ACETATE</b> 8.0 mEq/L
<b>CHLORIDE</b> 101.5 mEq/L	<b>CHLORIDE</b> 101.5 mEq/L
<b>DEXTRIOSE</b> 100 mg/dL	<b>DEXTRIOSE</b> 100 mg/dL
<b>BICARBONATE</b> 34.6 mEq/L	<b>BICARBONATE</b> 34.6 mEq/L

**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 42.26 parts purified water that meets ISO 19599 or AAMI RD2 water quality requirements. Use only with 45X bicarbonate (B) concentrate.

**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.

**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 4 bags are present.

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

**MANUFACTURER:** Fresenius Medical Care Renal Therapies Group, LLC Waltham, MA 02451 U.S.A. 1-800-323-5188

**What has not changed:**

- Catalog numbers have not changed
- Product offering remains the same
- Packaging remains the same

**Please familiarize yourself with the changes and how these may impact your storage and preparation of the product.**

If in need of further assistance, please contact Technical Services at 1-800-227-2572.  
Thank you for your continued support of Fresenius Medical Care North America.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Jaquith". The signature is fluid and cursive, with a long horizontal stroke at the end.

Stephen Jaquith,  
Sr. Product Manager Concentrates,  
Fresenius Medical Care Renal Technologies