U.S. Food and Drug Administration
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Medical Devices

Fresenius Medical Care North America, Naturalyte and Granuflo Acid Concentrate

Recall Class: Class I

Date Recall Initiated: March 29, 2012

Product: Naturalyte and Granuflo Acid Concentrate

Serial numbers for Naturalyte Liquid Acid Concentrate range from:
08-0231-4, 08-1001-0, 08-1201-8, 08-1231-3, 08-1251-1, 08-1301-4, 08-2201-5, 08-2231-2, 08-2251-0, 08-2301-3,08-2351-8, 08-3201-4, 08-3231-1, 08-3251-9, 08-3301-2, 08-4123-1, 08-4223-7, 08-4225-1, 08-4230- 2, 08-4231-0, 08-4323-5, 08-4325-1, 13-1251-1, 13-2201-5, 13-2231-2, 13-2251-0, 13-3231-1, 13-3251-9, 13-4123-1, 13-4220-1, 13-4225-1, 13-4325-1

Serial numbers for Naturalyte GranuFlo (powder) Acid Concentrate range from:
OFD1201-3B, OFD1251-3B, OFD2123-3B, OFD2201-38, OFD2220-3B, OFD2223-3B, OFD2225-3B, OFD2231-3 B, OFD2251-3B, OFD2301-3B, OFD2323-3 B, OFD2325-3B, OFD3201-3B, OFD3231-3B, OFD3251-3B, OFD3301-3B

This concentrate was manufactured and distributed from January 2008 through June 2012.

Use: The Naturalyte and Granuflo Dry Acid Concentrate are used in the treatment of acute and chronic renal failure during hemodialysis. The concentrate is formulated to be used with a three-stream hemodialysis machine, which is calibrated for acid and bicarbonate concentrates.

Recalling Firm:

Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

Reason for Recall:

The manufacturer is cautioning clinicians to be aware of the concentration of acetate or sodium diacetate (acetic acid plus acetate) contained in Fresenius' Naturalyte Liquid and Granuflo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death.

FDA has issued a general safety communication related to inappropriate prescription and resultant alkali dosing errors in the dialysate concentrates used in hemodialysis.

Public Contact:

Consumers may contact the firm at 1-800-662-1237.

FDA District: New England District Office

FDA Comments:

On March 29, 2012, the firm sent an Urgent Product Notification to their clinics and customers. This notification provided clinicians with prescribing information regarding the Naturalyte Liquid and Granuflo Acid Concentrate.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program[1] either online, by regular mail or by FAX.

Additional Links:

- FDA Safety Communication[2]
- Firm Urgent Product Notification [3]

Page Last Updated: 07/10/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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1. http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm

2. /MedicalDevices/Safety/AlertsandNotices/ucm305477.htm
3. http://www.fmcna.com/fmcna/idcplg?IdcService=GET_FILE&allowInterrupt=1&RevisionSelectionMethod=LatestReleased&Rendition=Primary&dDocName=PDF_300045654