Dialysate Concentrates Used in Hemodialysis: Safety Communication - Alkali Dosing Errors

[UPDATED 06/27/2012] FDA issued a Class I Recall notice for Fresenius Medical Care North America Naturalyte Liquid Acid Concentrate and Naturalyte GranuFlo (powder) 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.

For further information and list of Product Serial numbers please see the Class 1 Recall Notice.

[Posted 05/25/2012]

AUDIENCE: Nephrology, Nursing

ISSUE: FDA is notifying health care providers to consider the presence and quantity of acetate, citrate, and/or acetic acid in dialysate concentrates when determining the patients' dialysate prescription. The FDA received a complaint describing alkali dosing errors that occurred during hemodialysis using dialysate concentrates containing acetic acid and acetate. When metabolized, these potential sources of alkali can contribute to elevated bicarbonate levels in patients undergoing hemodialysis. This can contribute to metabolic alkalosis, which is a significant risk factor associated with cardiopulmonary arrest, low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia.

BACKGROUND: Dialysate is a solution prescribed by physicians for use in the treatment of acute and chronic renal failure during the hemodialysis procedure. The dialysate solution is used in combination with the hemodialysis machine and dialyzer to remove wastes from the blood.

Dialysate acid concentrate can contain acetic acid, acetate or citrate, and that these substances can be converted in the body to bicarbonate, potentially contributing to metabolic alkalosis. These substances typically are found in acid concentrate in amounts ranging from 1.5 to 8 mEq/L. This potential exists for all currently marketed dialysate concentrate products containing acetate, acetic acid, or citrate.

RECOMMENDATION: Health care providers should review the dialysate acid concentrate labeling for the specific concentrate that they prescribe t determine the components that can contribute to the patient's overall bicarbonate levels. The levels of acetate, citrate and/or acetic acid vary by formulation and by manufacturer. Be aware that metabolic alkalosis (pre-dialysis serum bicarbonate levels > or = to 27 mEq/L) has been associate with a higher risk of death in hemodialysis patients.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, o submit by fax to 1-800-FDA-0178

[06/27/2012 - Recall Notice [3] - FDA]
[05/25/2012 - Safety Communication [4] - FDA]

Links on this page:

1. http://www.fda.gov/MedWatch/report.htm
2. /Safety/MedWatch/HowToReport/DownloadForms/default.htm
3. /MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm309990.htm
4. /MedicalDevices/Safety/AlertsandNotices/ucm305477.htm

- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- For Government
- For Press

- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness
- International Programs
- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

U.S Department of **Health & Human Services**

Links on this page:

1. http://www.fda.gov/MedWatch/report.htm
2. /Safety/MedWatch/HowToReport/DownloadForms/default.htm
3. /MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm309990.htm
4. /MedicalDevices/Safety/AlertsandNotices/ucm305477.htm