FDA Safety Communication: Dialysate Concentrates and Alkali Dosing Errors with Hemodialysis

U.S. Food & Drug Administration

Date Issued: May 25, 2012

Audience:

- Health care professionals using dialysis equipment and prescribing dialysate concentrates, including nephrologists, nurses, and dialysis technicians
- Hospital and clinic administrators, medical officers, risk managers, and dialysis clinics

Medical Specialty: Nephrology

Product: All Hemodialysis Dialysate Concentrates Containing Acetate, Acetic Acid, or Citrate.

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 for hemodialysis is regulated as a medical device by the FDA.

Purpose:
To remind nephrologists, dialysis nurses and technicians about acetate, acetic acid and/or citrate levels in dialysate concentrates and the need to consider the impact of these substances when ordering or administering the patient’s dialysate prescription.

Summary of Problem and Scope:
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.

Health care professionals may not be aware that the 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.**

A recent report from the National Kidney Foundation 2011 Spring Clinical Meetings retrospectively evaluated 50 hemodialysis patients hospitalized in October 2010. Their outpatient dialysate prescription included a 35 mEq/L bicarbonate solution and an acid concentrate which contained 8 mEq/L of acetate (total bicarbonate of 43 mEq/L). At presentation, the patients' mean serum bicarbonate level was 31.3 mEq/L and 54 percent had a serum bicarbonate >30 mEq/L. (Pande S, Raja R, Bloom E, Chewaproug D, Dissanayake I. Effect of dialysate baths on serum bicarbonate levels in hemodialysis patients. American Journal of Kidney Disease 2011; 57(4): A75 (Abstract #234))

Recommendations for Health Care Providers:

- Be aware that metabolic alkalosis (pre-dialysis serum bicarbonate levels > or = to 27 mEq/L) has been associated with a higher risk of death in hemodialysis patients.
- Before writing the bicarbonate component of the dialysate prescription or using dialysate concentrates:
    - Review the dialysate acid concentrate labeling for the specific concentrate that you prescribe or use to determine the components that can contribute to the patient's bicarbonate level. The levels of acetate, citrate and/or acetic acid vary by product and manufacturer.
    - Be sure to understand how your specific hemodialysis device proportions (mixes) the acid and base concentrates.
    - Be aware that some dialysate acid concentrates contain acetate, citrate and acetic acid level combinations up to 8 mEq/L, and some products may contain both acetate and acetic acid.
- Discuss laboratory results with your patients as appropriate.

FDA Activities:
The FDA worked with Fresenius Medical Care, one manufacturer of dialysate concentrate, on a notice about this issue [1] [2] released to their customers on March 29, 2012.

The FDA continues to evaluate the scientific literature and adverse event reports about dialysates. The FDA will keep the public informed if any relevant new information becomes available.

Reporting Problems to the FDA:
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with Dialysate Concentrates, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [3]. Health care personnel employed by facilities that are subject to the FDA's user facility reporting

requirements [4] should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations. [4]

To help us learn as much as possible about the adverse events associated with Dialysate Concentrates, please include the following information in your reports, if available:

- Product Name
- Lot Number
- Manufacturer
- Relevant events prior and subsequent to the referenced problem
- Concomitant medical products
- Details of the adverse event and medical intervention (if required)

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV [5], 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

SOURCE [6]

Source URL (retrieved on *09/15/2014 - 9:32pm*):
http://www.mdtmag.com/news/2012/05/fda-safety-communication-dialysate-concentrates-and-alkali-dosing-errors-hemodialysis?qt-most_popular=0

Links:
[1] http://www.fmcna.com/fmcna/idcplg?IdcService=GET_FILE&allowInterrupt=1&RevisionSelectionMethod=LatestReleased&Rendition=Primary&dDocName=PDF_300045654
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