Vitaflo USA Renastart: Recall - Possible Health Risk Due To Incorrectly Labeled Cans

U.S. Food & Drug Administration

AUDIENCE: Pediatrics, Health Professionals, Consumers

ISSUE: Vitaflo USA has announced a voluntary recall of Renastart 14.11 oz (400g) cans, Batch Number 12832, because some of the product shipped throughout the United States during the period December 29, 2011 through January 26, 2012 was incorrectly labeled. Some immediate consequences of using the incorrectly labeled product may result in high potassium blood levels (hyperkalemia) or high sodium levels in the blood (hypernatremia). All other Vitaflo products, including Renastart cans in batches other than 12832 and Renastart packed in sachets, are not affected.

BACKGROUND: Renastart is a powdered medical food used in the dietary management of pediatric renal disease, for patients one year and older. Renastart 14.11oz (400g) product in cans is sold only in the United States. Following a customer complaint regarding the way the product was dissolving, Vitaflo determined that a small number of cans of a different product may have been wrongly labeled as Renastart.

RECOMMENDATION: Vitaflo USA is urging anyone who has any Renastart 14.11 oz (400g) cans Batch Number 12832 to immediately stop using the product and to contact Vitaflo to arrange return of the product, at Vitaflo's expense. All patients who have consumed any Renastart from this batch should contact their health care professional immediately to determine next steps, including nutritional management alternatives.

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, or submit by fax to 1-800-FDA-0178

[01/31/12 - Recall Notice [3] - FDA]
[01/31/12 - Vitaflo Product Label Photo [4]]

SOURCE [5]

Source URL (retrieved on *01/30/2015 - 2:07pm*):
http://www.mdtmag.com/news/2012/01/vitaflo-usa-renastart-recall-possible-health-risk-due-incorrectly-labeled-cans

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm289658.htm
[4] http://www.fda.gov/Safety/Recalls/ucm289661.htm
[5] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm289705.htm