Baxter

IMPORTANT PRODUCT INFORMATION

June 20, 2018

Dear Director of Materials Management:

Affected Products

Product Code	Product Description	Lot Number	Expiration Date	NDC
2A9018PrORX	PRX INFUVITE Adult Single Dose 10LIVI US	GY5919	08/2018	54643-7862-9
		GZ9290	08/2018	
		HG7655	12/2018	

Problem Description

Sandoz Canada Inc. has identified that the product code and lot numbers listed above include the incorrect strength of folic acid printed on the vial label. The strength of folic acid is printed as 600 mg on the label, and the correct strength is 600mcg as printed on the package insert and the carton. Please see the enclosed Sandoz Important Correction of Drug Information notification dated June 6, 2018. Baxter Healthcare Corporation (Baxter) distributes INFUVITE Adult Multiple Vitamins Injection for Sandoz.

Hazard Involved

Apart from the error on the label, the product has the appropriate quantity of folic acid. If the product is administered by healthcare professionals as prescribed, there is no risk to the patient.

Action to be taken by customers

Please complete the enclosed Baxter customer reply form confirming your receipt of this letter. The reply form can be returned by fax or email. Returning the form promptly will prevent you from receiving a repeat notice.

Further Information and support

Thank you for your cooperation. If you have additional questions, please contact Baxter Corporate Product Surveillance at 800-437-5176.

Sincerely,

Merle Goddard
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Sandoz Important Correction of Drug Information
Baxter Customer Reply Form

SANDOZ A Novartis Division

Sandoz Inc.
100 College Road West
Princeton, NJ 08540 USA
www.us.sandoz.com

Important Correction of Drug Information

June 6, 2018

SUBJECT: Notice to Healthcare Professional Regarding Baxter's Premier ProRx INFUVITE® ADULT Multiple Vitamins Injection Error on Vial #2 Label

Dear Healthcare Professional:

The purpose of this letter is to inform you of an issue with respect to an error on the label on Vial # 2 of Baxter's Premier ProRx INFUVITE® ADULT Multiple Vitamins Injection. Baxter's Infuvite Adult Multiple Vitamins Injection is manufactured by Sandoz Canada Inc., and distributed by Baxter. The 5 mL, 10 pack contains five (5) of Vial #1 and five (5) of Vial #2. One of each vial is required for a single dose.

Summary of an Error in the 5 mL Vial #2 label

The strength of Folic Acid is erroneously stated as 600 mg on the Vial #2 label. The correct strength is 600 mcg, as stated on the package insert and the carton.

Sandoz Inc. has evaluated all the approved INFUVITE® ADULT Multiple Vitamins Injection labels and has determined that this error was only on the Premier ProRx product Vial #2 label.

The table below summarizes the lots with labels impacted by this error.

Material Description	Lot	Expiration Date	NDC Code
PRX INFUVITE Adult Single Dose 10LIVI US	GY5919	08. 2018	54643-7862-9
PRX INFUVITE Adult Single Dose 10LIVI US	GZ9290	08. 2018	54643-7862-9
PRX INFUVITE Adult Single Dose 10LIVI US	HG7655	12. 2018	54643-7862-9

Apart from the error in the label, the product has the appropriate quantity of Folic Acid and is used as a single dose for patient administration. The product itself is considered safe for the patient as its quality and efficacy is not affected.

If the product is administered by healthcare professionals as prescribed, there is no risk to the patient due to the error on the Vial #2 label.

If you have any questions or comments on the information provided in this letter, please contact: Sandoz Quality Compliance Call Center at 1-800-525-2492, Email: qa.drugsafety@sandoz.com.

SANDOZ A Novartis Division

Sandoz Inc.
100 College Road West
Princeton, NJ 08540 USA
www.us.sandoz.com

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

Thank you again for your support of INFUVITE® ADULT Multiple Vitamins Injection.

Sincerely,
SANDOZ INC.

Anthony Maffia III,
Vice President, Regulatory Affairs