Heritage® Value Driven Medicine

URGENT: DRUG PRODUCT RECALL NOTIFICATION

May 29, 2019

Dear Valued Customer:

Heritage Pharmaceuticals Inc. ("Heritage") East Brunswick, New Jersey, is initiating a voluntary recall of Amikacin Sulfate Injection, USP, 1g/4 mL (250mg/mL), Lot: VEAC025, Expiry Date: October 2019 to the consumer level (Wholesalers and their sub consignees such as hospitals, pharmacies and physicians). This drug product is manufactured by Emcure Pharmaceuticals Ltd. ("Emcure") and distributed by Heritage. The voluntary recall is being initiated due to microbial growth having been detected in one unreleased sublot Lot VEAC025, which may indicate a lack of sterility in the other sublots.

Product Name:	**Amikacin Sulfate Injection USP**
Dosage / Package:	**1 g/ 4 mL (250 mg/ml)**
NDC:	**2315529042**
Lot(s):	**VEAC025, Expiry Date: October 2019**

Please note that Amikacin lot VEAC025 is a terminally-sterilized product which was manufactured with total 7 sublots (A, B, C, D, E, F, G) with expiration date of October 2019. Each sublot is individually subjected to sterility test. During initial release testing, a positive result was seen in the sterility test of, sublot D. During the detailed investigation & impact assessment the most probable cause for this occurrence, was attributed to Laboratory Contamination of the test sample. As a precaution, the sublot D was rejected. Rest of all 6 sublots were released which were meeting all the approved specifications including sterility testing were released post a comprehensive investigation by concluding that there was no impact on product quality. Although Emcure remains confident that there are no adverse quality or safety issues with respect to the terminally-sterilized Amikacin lot VEAC025, during a recent re assessment of this investigation, the firm has decided to recall the subject product lot out of an abundance of caution.

Heritage began shipping the subject product lots on June 22, 2018 which were distributed to wholesalers and distributors in United States between June 2018 and August 2018.

Immediately examine your inventory and quarantine subject product lot. In addition, if you have further distributed this product, please identify your customers and notify them at once about this product recall. Please send a copy of this "Recall Notification Letter" with "Recall Response Form" to your customers and request them to return the "Recall Response Form" to Heritage designated recall service provider [Qualanex], as indicated below in this letter. Qualanex will provide your customers with a recall return package that will include a UPS postage paid product return label to return any recalled product to the address provided below.

23155-00201-01000404
AMERISOURCEBERGEN
101 NORFOLK ST
MANSFIELD, MA 2048

HERITAGE PHARMACEUTICALS INC.
ONE TOWER CENTER BLVD., SUITE 1700 ▪ EAST BRUNSWICK, NJ 07724 ▪ T: 732-429-1000 ▪ F: 732-429-1001 ▪ WWW.HERITAGEPHARMA.COM

Please take the following actions:

1. Check your inventory to see if you have any of the recalled product in stock. If so, place the product under quarantine and do not continue to use or distribute.
2. Return product to the following address:

   Heritage Pharmaceuticals Inc.
   c/o Qualanex, LLC
   1410 Harris Road
   Libertyville, Illinois 60048
   1-800-505-9291

   Please use enclosed UPS postage paid product return label to return any recalled products.
3. Complete the enclosed "Recall Response Form" and return via fax to **1-847-737-3719** or email to **recall@qualanex.com**. Consumers with any returns related questions should contact Qualanex at 1-800-505-9291 (Monday – Friday, 8:00 am – 5:00 pm EST) and or **recall@qualanex.com**.

Any adverse reactions or quality problems associated with the use of this product may be reported to ProPharma at **1-866-901-3784** at any time, and any such problems may also be reported to FDA's MedWatch Adverse Event Reporting program either by phone, online, by 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.

We apologize for any inconvenience caused by this product recall, and we appreciate your cooperation and support.

This recall is made with the full knowledge of the U.S. Food and Drug Administration.

Sincerely,

May 29, 2019

Jignesh Kahodariya
Associate Director, Quality and Compliance

See product labeling on next page for ease of identifying the product.

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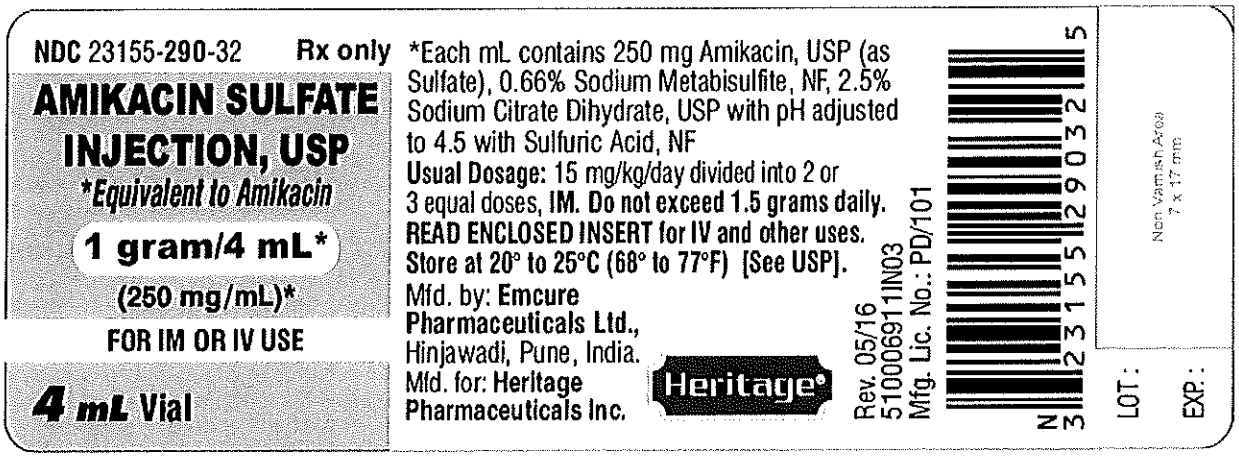
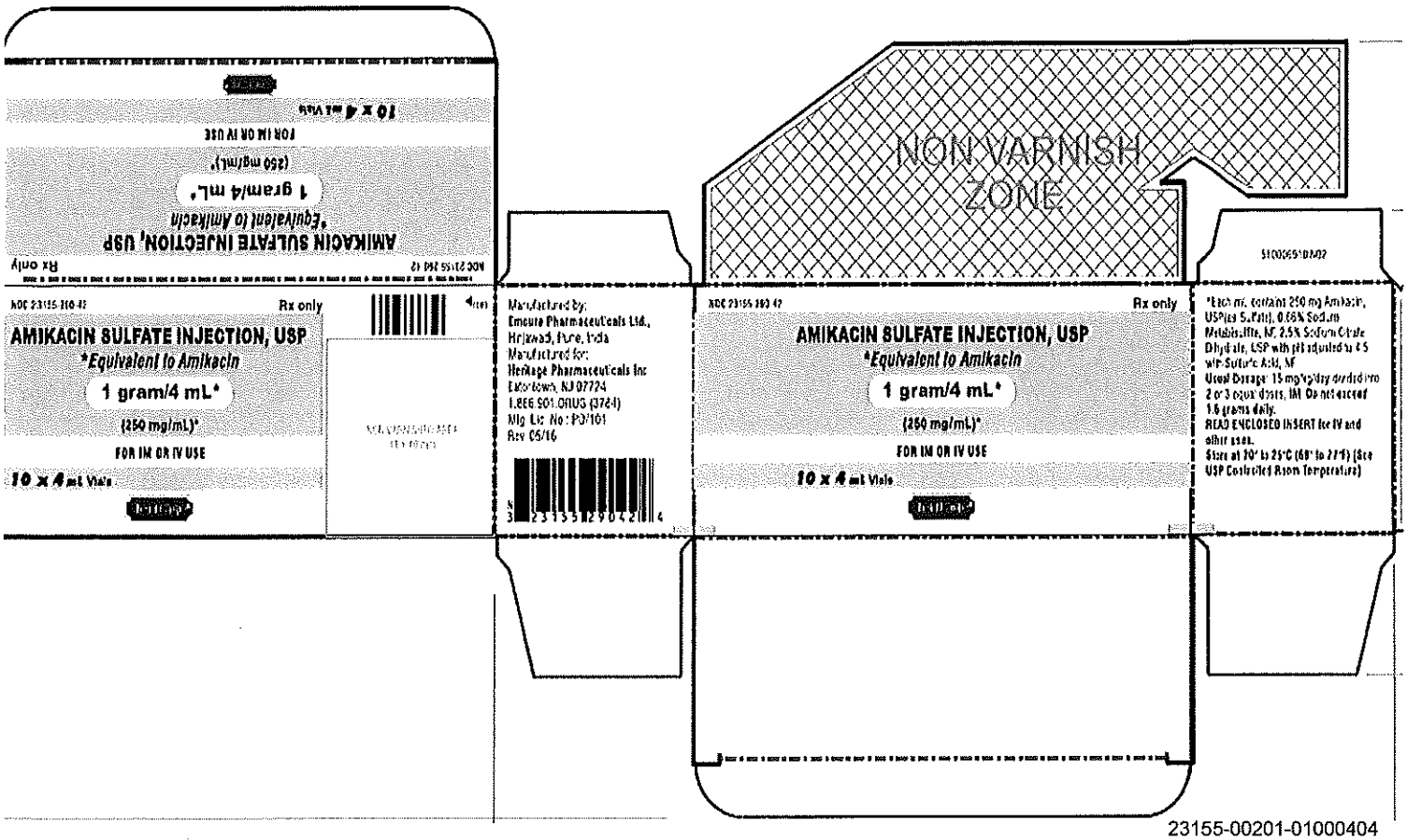
Amikacin Sulfate Injection USP 1 g/ 4 mL (250 mg/ml) Label



Amikacin Sulfate Injection USP 1 g/ 4 mL (250 mg/ml) Carton



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