

## IN THIS SECTION



## FDA ANNOUNCEMENT

# Heritage Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Amikacin Sulfate Injection, USP 1gm/4 mL (250mg/mL) and Prochlorperazine Edisylate Injection, USP 10mg/2mL (5mg/mL) as a Result of a Sterility Test Failure

## Summary

**Company Announcement Date:**

May 28, 2019

**FDA Publish Date:**

May 28, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

Sterility Failure

**Company Name:**

Heritage Pharmaceuticals Inc.

**Brand Name:**

Heritage

**Product Description:**

Amikacin Sulfate Injection, USP, 1g/4 mL (250mg/mL) and Prochlorperazine Edisylate Injection, USP, 10mg/2mL (5mg/mL)

## FDA Announcement

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 and Prochlorperazine Edisylate Injection, USP, 10mg/2mL (5mg/mL), Lot: VPCA172, Expiry Date: April 2020, to the consumer level. These drug products are 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 subplot of Lot VPCA172 and one unreleased subplot Lot VEAC025, which may indicate a lack of sterility in the other sublots.

Non-sterile injectable products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, organ damage or death. To date, Heritage has not received adverse event reports related to this event.

Amikacin Sulfate Injection is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including *Pseudomonas* species, *Escherichia coli*, species of indole-positive and indole-negative *Proteus*, *Providencia* species, *Klebsiella-Enterobacter-Serratia* species, and *Acinetobacter (Mima-Herellea)* species.

Amikacin Sulfate Injection was manufactured in a sealed vial with a printed label affixed to the vial. Ten (10) labeled vials were packed into a carton along with a leaflet. Fifty-six (56) cartons were packed into one shipper box. Heritage began shipping Amikacin Sulfate Injection, USP, 1g/4 mL (250mg/mL), NDC # 23155-290-42, Lot: VEAC025 on June 22, 2018, and the entire lot was distributed to wholesalers and distributors in United States between June 2018, and August 2018.

Prochlorperazine Edisylate Injection is indicated to control severe nausea and vomiting and for the treatment of schizophrenia. Prochlorperazine has not been shown effective in the management of behavioral complications in patients with mental retardation.

Prochlorperazine Edisylate Injection was manufactured in a sealed vial with a printed label affixed to the vial. Five (5) labeled vials were packed into one formed PVC tray. Two (2) PVC trays were packed into a carton along with a leaflet. Twenty (20) cartons were packed into one shipper box. Heritage began shipping Prochlorperazine Edisylate Injection, USP, 10mg/2mL (5mg/mL), NDC # 2315529442, Lot: VPCA172, on October 31, 2018, which was distributed to wholesalers and distributors in United States between October 2018, and November 2018.

Qualanex is notifying Heritage consignees by recall notification and arranging for return of the recalled product.

Consumers should contact their doctor for further guidance and potential change of treatment before they stop taking this drug product. Pharmacies and healthcare facilities that have the products subject to this recall should immediately stop dispensing this drug product and consumers should immediately stop using any product within these specific lots.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Consumers with questions regarding this recall should contact Qualanex at 1-800-505-9291 Monday – Friday, 8:00 am – 5:00 pm, EST and or [recall@qualanex.com](mailto:recall@qualanex.com) (<mailto: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.

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

- Complete and submit the report Online (</node/360543>)
- Regular Mail or Fax: Download form (</node/360547>) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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## FDA Contact Information

### Consumers:

Heritage Pharmaceuticals Inc. c/o Qualanex, LLC

☎ 1-800-505-9291

✉ [recall@qualanex.com](mailto:recall@qualanex.com) (<mailto:recall@qualanex.com>)

### Media:

Heritage Pharmaceuticals Inc. c/o Qualanex, LLC

☎ 1-800-505-9291

✉ [recall@qualanex.com](mailto:recall@qualanex.com) (<mailto:recall@qualanex.com>)

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## Product Photos

**NDC 23155-290-32 Rx only**

**AMIKACIN SULFATE INJECTION, USP**  
*\*Equivalent to Amikacin*

**1 gram/4 mL\***  
 (250 mg/mL)\*


**FOR IM OR IV USE**

**4 mL Vial**

\*Each mL contains 250 mg Amikacin, USP (as Sulfate), 0.66% Sodium Metabisulfite, NF, 2.5% Sodium Citrate Dihydrate, USP with pH adjusted to 4.5 with Sulfuric Acid, NF  
**Usual Dosage:** 15 mg/kg/day divided into 2 or 3 equal doses, **IM. Do not exceed 1.5 grams daily.**  
**READ ENCLOSED INSERT for IV and other uses.**  
**Store at 20° to 25°C (68° to 77°F) [See USP].**  
 Mfd. by: **Emcure Pharmaceuticals Ltd.,** Hinjawadi, Pune, India.  
 Mfd. for: **Heritage Pharmaceuticals Inc.**

**Heritage®**

Rev. 05/16  
 510006911IN03  
 Mfg. Lic. No.: PD/101



N 312315512903215

LOT: \_\_\_\_\_  
 EXP: \_\_\_\_\_

Non Varnish Area  
 7 x 17 mm

**NDC 23155-294-31**

**PROCHLORPERAZINE EDISYLATE INJECTION, USP**

**10 mg/2 mL**  
 (5 mg/mL)

**FOR DEEP IM OR IV USE ONLY.**  
**NOT FOR SC USE.**

**2 mL Vial Rx only**

**PROTECT FROM LIGHT.**  
 Mfg.Lic.No. : PD/101  
 Mfg by: **Emcure Pharmaceuticals Ltd.,** Hinjawadi, Pune, India.  
 Mfg for: **Heritage Pharmaceuticals Inc.**

**Heritage®**

Rev. 09/17  
 510007141IN03



N 312315512943116

Lot: \_\_\_\_\_  
 Exp.: \_\_\_\_\_

NON VARNISHED AREA  
 14.5 x 7 mm

➡ More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls)