Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: February 26, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Heritage Pharmaceuticals Inc. – RECALL [Drug]

AFFECTED PRODUCT: **Colistimethate for Injection, USP and Rifampin for Injection, USP**

SUMMARY: **Unclassified Recall; The products are being recalled due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.**

Colistimethate for Injection, USP, 150 mg Single-Dose vial (NDC 23155-193-31) and Rifampin for Injection, USP, 600 mg Single-Dose vial (NDC 23155-340-31) manufactured by Emcure Pharmaceuticals Ltd. and distributed by Heritage. Both products are sold in single vial mono-cartons in case packs of ten (10).

The lot numbers with expiry date being recalled are: Colistimethate for Injection

Lot No.	Exp. Date
VCOA002	9/30/2014
VCOA003	10/31/2014
VCOA004	10/31/2014
VCOA005	1/31/2015
VCOA006	3/31/2015
VCOA007	9/30/2015
VCOA008	12/31/2015
VCOA009	2/29/2016
VCOA010	10/31/2016
VCOA011	10/31/2016

Rifampin for Injection

Lot No.

VRIA002
VRIA003
VRIA004

Exp. Date

8/31/2016
9/30/2016
9/30/2016

The products were distributed to hospitals, wholesalers and distributors nationwide from December 2012 through January 2015 (Colistimethate) and from October 2014 through January 2015 (Rifampin).

SUGGESTED ACTION: **For consumer inquiry only. Any questions about returning unused product should be directed to the customer call center at (866) 901-1230 M-F 9am-5pm EST. Healthcare workers who have medical questions about Colistimethate for Injection, USP, 150 mg base/vial and Rifampin for Injection USP, 600 mg/vial may contact Heritage Medical Affairs (732-429-1000, Ext. 101) M-F 9am-5pm EST.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Heritage Pharmaceuticals Initiates a Nationwide Voluntary Recall of Colistimethate for Injection USP, 150 mg and Rifampin for Injection USP, 600 mg/vial Due to a Lack of Sterility Assurance

Contact:
Consumer:
1-800-505-9291

FOR IMMEDIATE RELEASE — February 24, 2015 — Eatontown, NJ, Heritage Pharmaceuticals Inc. (Heritage) today announced the voluntary nationwide recall of ten (10) lots of Colistimethate for Injection, USP, 150 mg Single-Dose vial (NDC 23155-193-31) and three (3) lots of Rifampin for Injection, USP, 600 mg Single-Dose vial (NDC 23155-340-31) manufactured by Emcure Pharmaceuticals Ltd. and distributed by Heritage. Both products are sold in single vial mono-cartons in case packs of ten (10). Heritage has initiated this voluntary recall of Colistimethate for Injection, USP, 150 mg Single-Dose vial and Rifampin for Injection USP, 600 mg Single-Dose vial to the user level due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.

Intravenous administration of non-sterile injection products to a normally sterile site may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity (permanent organ damage), or fatal outcome. To date, Heritage is not aware of any adverse patient events resulting from the use of the subject product lots.

The lot numbers with expiry date being recalled are: Colistimethate for Injection

Lot No.
VCOA002
VCOA003
VCOA004
VCOA005
VCOA006
VCOA007
VCOA008

VCOA009	9/30/2014
VCOA010	10/31/2014
VCOA011	10/31/2014
Exp. Date	1/31/2015
9/30/2014	3/31/2015
10/31/2014	9/30/2015
10/31/2014	12/31/2015
1/31/2015	2/29/2016
3/31/2015	10/31/2016
9/30/2015	10/31/2016
12/31/2015	
2/29/2016	
10/31/2016	
10/31/2016	

Rifampin for Injection

Lot No.	8/31/2016
VRIA002	9/30/2016
VRIA003	9/30/2016
VRIA004	
Exp. Date	

The products were distributed to hospitals, wholesalers and distributors nationwide from December 2012 through January 2015 (Colistimethate) and from October 2014 through January 2015 (Rifampin). Colistimethate is indicated for the treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacteria. Rifampin is indicated for the treatment of all forms of tuberculosis.

Customers are being notified by fax, email, UPS, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of, and return the recalled lots of product. Customers who may have further distributed these products have been requested to identify their customers and notify them at once of this product recall.

Any questions about returning unused product should be directed to the customer call center at (866) 901-1230 M-F 9am-5pm EST. Healthcare workers who have medical questions about Colistimethate for Injection, USP, 150 mg base/vial and Rifampin for Injection USP, 600 mg/vial may contact Heritage Medical Affairs (732-429-1000, Ext. 101) M-F 9am-5pm EST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Report Program either 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.

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

About Heritage Pharmaceuticals Inc.

Heritage Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development, licensing, sales and marketing of prescription pharmaceutical products.

CUSTOMER SUPPORT:
Customer Service:
Toll free: 1-800-505-9291

HERITAGE SCIENTIFIC AFFAIRS:
Dr. Pablo Davila
(732) 429-1000, Ext. 101

Source: Heritage Pharmaceuticals Inc.

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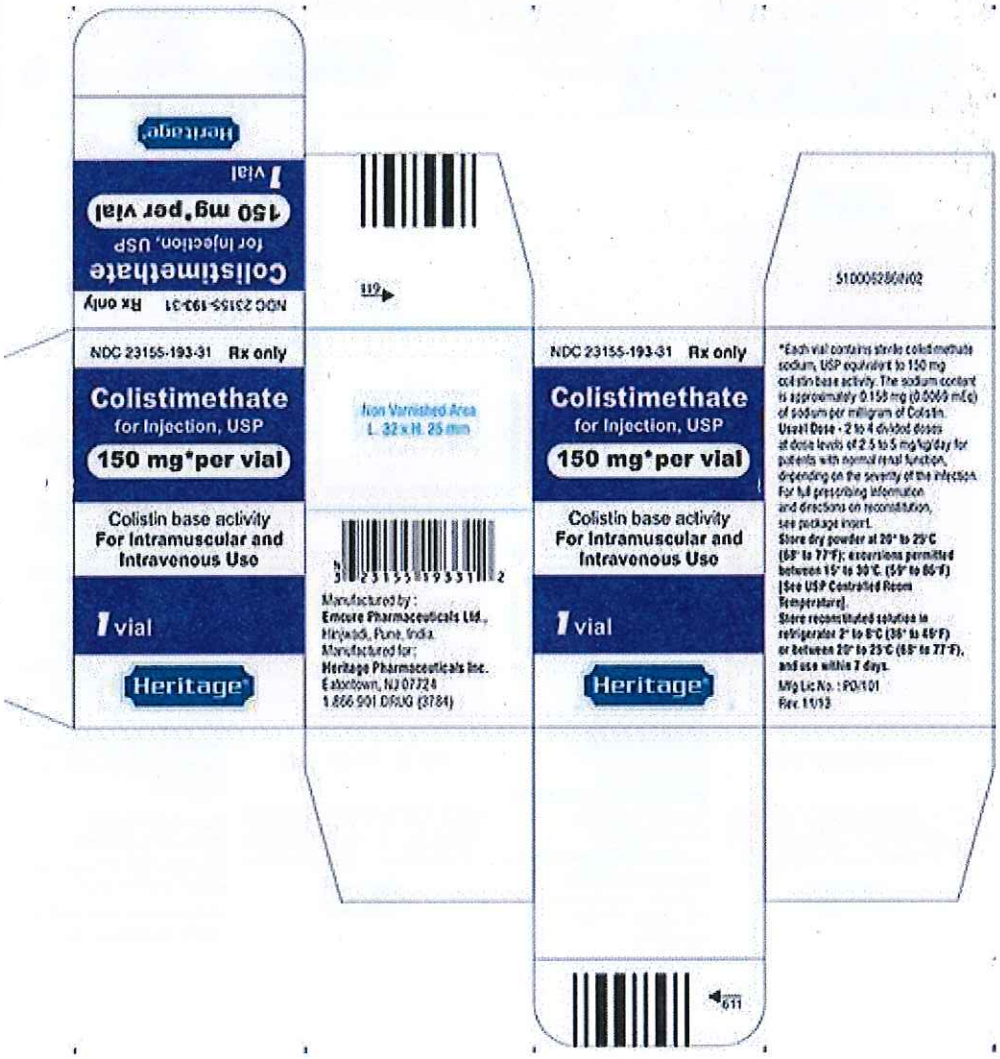
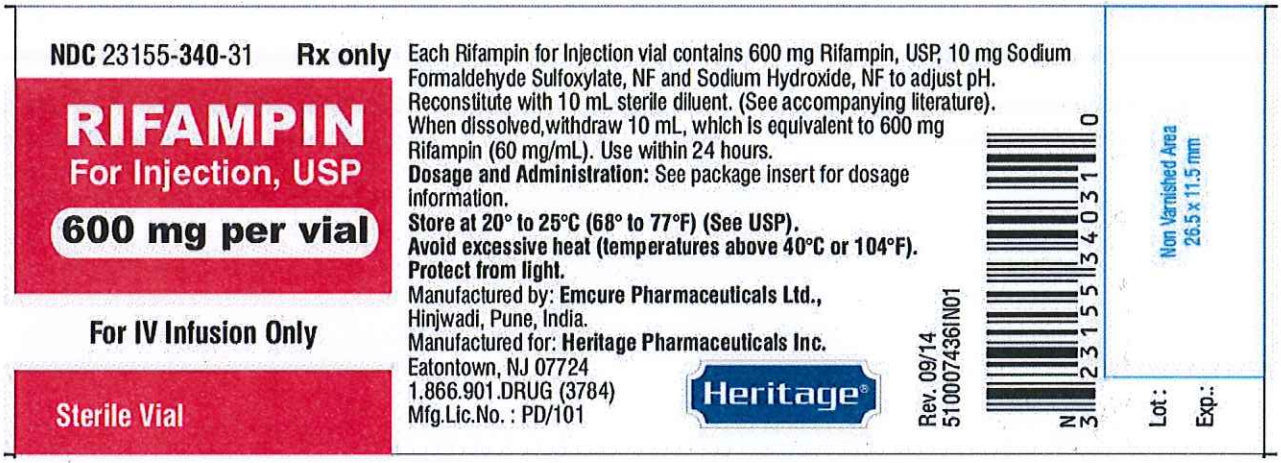
U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Heritage Pharmaceuticals Initiates a Nationwide Voluntary Recall of Colistimethate for Injection USP, 150 mg and Rifampin for Injection USP, 600 mg/vial Due to a Lack of Sterility Assurance Photo




NDC 23155-193-31
Rx only
Colistimethate
for Injection, USP
150 mg*per vial
Colistin base activity
For Intramuscular and
Intravenous Use
1 vial
*This vial contains colistimethate sodium, USP equivalent to 150 mg colistin base activity. The sodium content is approximately 0.158 mg (0.0069 mEq) of sodium per milligram of Colistin.
Usual Dosage: See insert.
For full prescribing information and directions on reconstitution, see package insert.
Store dry powder at 20° to 25°C (68° to 77°F); [See USP]. Store reconstituted solution in refrigerator 2° to 8°C (36° to 46°F) or between 20° to 25°C (68° to 77°F), and use within 7 days.
Manufactured by : Emcure Pharmaceuticals Ltd., Hinjwadi, Pune, India.
Manufactured for : Heritage Pharmaceuticals Inc.
Mfg.Lic.No. : PD/101
510006285IN02
Rev. 11/13
Heritage
NON VARNISHED AREA
25 x 8.5 mm
LOT :
EXP. :


NDC 23155-340-31 Rx only
RIFAMPIN
For Injection, USP
600 mg per vial
For IV Infusion Only
1 Sterile Vial
Heritage
Non Varnished Area
40 x 40 mm
Manufactured by:
Emcure Pharmaceuticals Ltd.,
Hinjwadi, Pune, India.
Manufactured for:
Heritage Pharmaceuticals Inc.
Eatontown, NJ 07724
1.866.901.DRUG (3784)
Mfg.Lic.No. : PD/101
Rev. 09/14
Non Varnished Area
Space for 2D Barcode
40 x 40 mm
510007435IN01
Each Rifampin for Injection vial contains 600 mg Rifampin, USP, 10 mg Sodium Formaldehyde Sulfoxylate, NF and Sodium Hydroxide, NF to adjust pH.
Reconstitute with 10 mL sterile diluent. (See accompanying literature). When dissolved, withdraw 10 mL, which is equivalent to 600 mg Rifampin (60 mg/mL). Use within 24 hours.
Dosage and Administration: See package insert for dosage information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Avoid excessive heat (temperatures above 40°C or 104°F). Protect from light.



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