SAMFORD UNIVERSITY GLOBAL DRUG INFORMATION SERVICE'S

NEW DRUG FAX SHEET

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NATIONWIDE RECALL OF SEVERAL LOTS OF COLISTIMETHATE FOR INJECTION

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding a voluntary national recall of several lots of colistimethate for injection due to issues associated with product sterility. The verbatim safety alert can be found below. If you need further information, please contact the Samford University Global Drug Information Service at (205) 726-2659.

AUDIENCE: Pharmacy

ISSUE: Heritage Pharmaceuticals Inc. 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. Heritage has initiated this voluntary recall to the user level due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility. See the Press Release for a listing of affected lot numbers.

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.

BACKGROUND: 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.

RECOMMENDATION: 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.

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
- Download form 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

Read the MedWatch safety alert, including a link to the firm press release, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm435616.htm

Prepared by: Maisha Kelly Freeman, PharmD, MS, BCPS, FASCP