



California Drug Recall Information



Recall Name

**Heritage Pharmaceuticals Recalls
Colistimethate for Injection and Rifampin for Injection
Due to a Lack of Sterility Assurance**

Recall Date	Product Description	Recalling Firm	Recall Reason																														
2/24/15	<ul style="list-style-type: none"> Colistimethate for Injection, USP; 150mg Single-Dose Vial NDC# 23155-193-31 Rifampin for Injection, USP 600mg Single-Dose Vial NDC# 23155-340-31 	<p>Heritage Pharmaceuticals, Inc. Eatontown, NJ</p> <p>[manufactured by Emcure Pharmaceuticals Ltd.]</p>	<p><i>Due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.</i></p>																														
Recall Class	Product Identification	Distribution	Affected Dates																														
N/A	<p>Colistimethate for Injection:</p> <table border="0"> <thead> <tr> <th><u>Lot No.</u></th> <th><u>Exp. Date</u></th> </tr> </thead> <tbody> <tr><td>VCOA002</td><td>9/30/2014</td></tr> <tr><td>VCOA003</td><td>10/31/2014</td></tr> <tr><td>VCOA004</td><td>10/31/2014</td></tr> <tr><td>VCOA005</td><td>1/31/2015</td></tr> <tr><td>VCOA006</td><td>3/31/2015</td></tr> <tr><td>VCOA007</td><td>9/30/2015</td></tr> <tr><td>VCOA008</td><td>12/31/2015</td></tr> <tr><td>VCOA009</td><td>2/29/2016</td></tr> <tr><td>VCOA010</td><td>10/31/2016</td></tr> <tr><td>VCOA011</td><td>10/31/2016</td></tr> </tbody> </table> <p>Rifampin for Injection:</p> <table border="0"> <thead> <tr> <th><u>Lot No.</u></th> <th><u>Exp. Date</u></th> </tr> </thead> <tbody> <tr><td>VRIA002</td><td>8/31/2016</td></tr> <tr><td>VRIA003</td><td>9/30/2016</td></tr> <tr><td>VRIA004</td><td>9/30/2016</td></tr> </tbody> </table>	<u>Lot No.</u>	<u>Exp. Date</u>	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	<u>Lot No.</u>	<u>Exp. Date</u>	VRIA002	8/31/2016	VRIA003	9/30/2016	VRIA004	9/30/2016	CA, nationwide	<p>Distribution Dates for</p> <ul style="list-style-type: none"> Colistimethate: December 2012 through January 2015 Rifampin: October 2014 through January 2015
<u>Lot No.</u>	<u>Exp. Date</u>																																
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																																
<u>Lot No.</u>	<u>Exp. Date</u>																																
VRIA002	8/31/2016																																
VRIA003	9/30/2016																																
VRIA004	9/30/2016																																

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/Recalls/ucm435560.htm>