

URGENT: DRUG RECALL

July 30, 2018

PRODUCT	<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="text-align: center;">Product</th> <th style="text-align: center;">NDC Number</th> <th style="text-align: center;">Size</th> <th style="text-align: center;">Lot Number</th> <th style="text-align: center;">Expiry Date</th> </tr> </thead> <tbody> <tr> <td>Doxycycline Hyclate Tablets, USP 100mg</td> <td style="text-align: center;">0904-0430-04</td> <td style="text-align: center;">3 x 10 Unit Dose</td> <td style="text-align: center;">71545AA</td> <td style="text-align: center;">07-2019</td> </tr> </tbody> </table> <p style="margin: 0;">Distributed by: Major Pharmaceuticals 17177 N. Laurel Park Dr., Suite 233 Livonia, MI 48152</p> <p style="margin: 0; text-align: right;">Recall Issued by: West-Ward Pharmaceuticals Eatontown, NJ 07724</p>	Product	NDC Number	Size	Lot Number	Expiry Date	Doxycycline Hyclate Tablets, USP 100mg	0904-0430-04	3 x 10 Unit Dose	71545AA	07-2019
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REASON	<p>We have been informed by West-Ward that they are voluntarily recalling to the Retail Level the product indicated in the above table. This recall was initiated due to “out-of-specification” results for dissolution test. A medical assessment has been completed and indicated that no drug safety issues would be expected. All other testing parameters for this lot were within specification.”</p>										
ACTIONS TO BE TAKEN	<ol style="list-style-type: none"> 1. Stop distributing and quarantine the affected lot. 2. Please carry out a physical count and record this data on the Business Reply Form / Packing Slip which is included with this letter. 3. Fax the Business Reply Form, even if you do not have the recalled product to 1-888-627-4935 or email to harvarddrug3123@stericycle.com. 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <p style="text-align: center; margin: 5px 0;">Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 3123</p> 5. If you have further distributed the product, please notify your Wholesale / Retail customers immediately and have them return the product back to you. 										
OTHER INFORMATION	<p>This recall is being carried out to the RETAIL LEVEL and is only for the specific product / lot listed above. No other lots, packages, or formulations are being recalled.</p> <p>This product was shipped from our Indianapolis warehouse between 10/31/17 and 02/20/18.</p> <p>For questions regarding returns, please contact Stericycle at 1-888-243-5547. For medical-related questions, please contact West-Ward at 1-877-233-2001 between 9:00am – 5:00pm EST, Monday through Friday or your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.</p> <p>To ensure proper credit, please return recalled merchandise before <u>October 31, 2018</u>. Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.</p> <p>This recall is being made with the knowledge of the FDA. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.</p>										