

URGENT: DRUG RECALL

July 2, 2018

PRODUCT	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Product</th> <th style="width: 20%;">NDC Number</th> <th style="width: 15%;">Size</th> <th style="width: 15%;">Lot Number</th> <th style="width: 20%;">Expiry Date</th> </tr> </thead> <tbody> <tr> <td rowspan="6" style="vertical-align: top;">Enalapril Maleate Tablets, USP 2.5 mg</td> <td rowspan="6" style="vertical-align: top;">0904-5609-61</td> <td rowspan="6" style="vertical-align: top;">10 x 10 Unit Dose</td> <td>T-01083</td> <td>08/2018</td> </tr> <tr> <td>DR10447A</td> <td>09/2018</td> </tr> <tr> <td>DS10201A</td> <td>07/2019</td> </tr> <tr> <td>DS10201B</td> <td>08/2019</td> </tr> <tr> <td>DS10201C</td> <td>08/2019</td> </tr> <tr> <td>DS10319A</td> <td>10/2019</td> </tr> <tr> <td rowspan="6" style="vertical-align: top;">Enalapril Maleate Tablets, USP 5 mg</td> <td rowspan="6" style="vertical-align: top;">0904-5502-61</td> <td rowspan="6" style="vertical-align: top;">10 x 10 Unit Dose</td> <td>T-01082</td> <td>08/2018</td> </tr> <tr> <td>DR10443A</td> <td>12/2018</td> </tr> <tr> <td>DR10445A</td> <td>09/2018</td> </tr> <tr> <td>DR10445B</td> <td>03/2019</td> </tr> <tr> <td>DR10725A</td> <td>07/2019</td> </tr> <tr> <td>DS10024A</td> <td>10/2019</td> </tr> <tr> <td></td> <td></td> <td></td> <td>DS10040A</td> <td>10/2019</td> </tr> </tbody> </table> <p style="margin-top: 5px;">Distributed by: Major Pharmaceuticals 17177 N. Laurel Park Dr., Suite 233 Livonia, MI 48152</p> <p style="text-align: right; margin-top: 5px;">Recall Issued by: Wockhardt Limited</p>	Product	NDC Number	Size	Lot Number	Expiry Date	Enalapril Maleate Tablets, USP 2.5 mg	0904-5609-61	10 x 10 Unit Dose	T-01083	08/2018	DR10447A	09/2018	DS10201A	07/2019	DS10201B	08/2019	DS10201C	08/2019	DS10319A	10/2019	Enalapril Maleate Tablets, USP 5 mg	0904-5502-61	10 x 10 Unit Dose	T-01082	08/2018	DR10443A	12/2018	DR10445A	09/2018	DR10445B	03/2019	DR10725A	07/2019	DS10024A	10/2019				DS10040A	10/2019
Product	NDC Number	Size	Lot Number	Expiry Date																																					
Enalapril Maleate Tablets, USP 2.5 mg	0904-5609-61	10 x 10 Unit Dose	T-01083	08/2018																																					
			DR10447A	09/2018																																					
			DS10201A	07/2019																																					
			DS10201B	08/2019																																					
			DS10201C	08/2019																																					
			DS10319A	10/2019																																					
Enalapril Maleate Tablets, USP 5 mg	0904-5502-61	10 x 10 Unit Dose	T-01082	08/2018																																					
			DR10443A	12/2018																																					
			DR10445A	09/2018																																					
			DR10445B	03/2019																																					
			DR10725A	07/2019																																					
			DS10024A	10/2019																																					
			DS10040A	10/2019																																					
REASON	<p>We have been informed by Wockhardt that they are voluntarily recalling to the Retail Level the products indicated in the above table. This recall was initiated due to “out-of-specification results for the Enalapril Diketopiperazine degradation product during commercial stability.”</p>																																								
ACTIONS TO BE TAKEN	<ol style="list-style-type: none"> 1. Stop distributing and quarantine the affected lots. 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 1-877-270-9245 or email to harvarddrug2736@stericycle.com. 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <div style="text-align: center; margin: 10px 0;"> Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 2736 </div> 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>These products were shipped from our Indianapolis warehouse between 10/24/16 and 06/20/18.</p> <p>For questions regarding returns, please contact Stericycle at 1-877-546-0121. For medical-related questions, please contact Wockhardt Limited customer care at 1-800-445-4290 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>September 30, 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>																																								