

URGENT: DRUG RECALL

April 26, 2019

PRODUCT	<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 30%;">Product</th> <th style="width: 20%;">NDC Number</th> <th style="width: 20%;">Size</th> <th style="width: 15%;">Lot Number</th> <th style="width: 15%;">Expiry Date</th> </tr> </thead> <tbody> <tr> <td>Losartan Potassium Tablets, USP 25mg</td> <td>0904-6391-61</td> <td>10 x 10 Unit Dose</td> <td>R-00473</td> <td>07-2019</td> </tr> <tr> <td rowspan="2">Losartan Potassium Tablets, USP 50mg</td> <td rowspan="2">0904-6390-61</td> <td rowspan="2">10 x 10 Unit Dose</td> <td>R-00498</td> <td>08-2019</td> </tr> <tr> <td>R-00568</td> <td>10-2019</td> </tr> <tr> <td>Losartan Potassium Tablets, USP 100mg</td> <td>0904-6389-61</td> <td>10 x 10 Unit Dose</td> <td>R00759D</td> <td>06-2020</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: Torrent Pharmaceuticals Ltd.</p>	Product	NDC Number	Size	Lot Number	Expiry Date	Losartan Potassium Tablets, USP 25mg	0904-6391-61	10 x 10 Unit Dose	R-00473	07-2019	Losartan Potassium Tablets, USP 50mg	0904-6390-61	10 x 10 Unit Dose	R-00498	08-2019	R-00568	10-2019	Losartan Potassium Tablets, USP 100mg	0904-6389-61	10 x 10 Unit Dose	R00759D	06-2020
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REASON	<p>We have been informed by Torrent Pharmaceuticals Limited that they are voluntarily recalling the products indicated in the above table. This recall was initiated due to “the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity in the API is N-Methylnitrosobutyric acid (NMBA).”</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 1-866-654-0725 or email to HarvardDrug10088@stericycle.com. 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <div style="margin-left: 40px;"> Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 10088 </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 products / lots listed above. No other lots, packages, or formulations are being recalled.</p> <p>These products were shipped from our Indianapolis warehouse between 09/18/2017 and 02/13/2019.</p> <p>For questions regarding returns, please contact Stericycle at 1-888-731-7952. For medical-related questions, please contact Torrent Pharma Inc. at 1-800-912-9561 between 8:00am – 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>July 30, 2019</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>																						



BUSINESS REPLY FORM / PACKING SLIP

Please make a copy of this form to include with your product return shipment.

Major Pharmaceuticals
Livonia, MI 48152

April 26, 2019

Products: Losartan Potassium Tablets, USP 25mg, 50mg and 100mg
Affected NDC Numbers: 0904-6391-61, 0904-6390-61 and 0904-6389-61
Affected Lot Numbers: R-00473 (25mg), R-00498 & R-00568 (50mg), R00759D (100mg)
Exp. Dates: 07-2019 (25mg), 08-2019 & 10-2019 (50mg), 06-2020 (100mg)
Package Size: Unit Dose Cartons of 100 Tablets

Your timely response to the recall notification is requested. Please fill out and fax this reply form within five (5) days, even if you do not have the recalled product. Thank you.

Please complete and fax or email to: **Stericycle at: Fax: 1-866-654-0725**
Email: HarvardDrug10088@stericycle.com

Wholesaler Name: _____ Wholesaler Acct #: _____

Debit Memo Number: _____

Signature: _____ Title: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Please check one:

- We do not have any of the recalled products on hand.**
- We have quarantined the following recalled product(s) and will return them as requested:**

Affected Lot Numbers: Losartan Potassium Tablets

NDC / UPC Number	Product Strength	Lot Number	Expiration Date	Whole Units on Hand	Partial Units on Hand
0904-6391-61 3 09046 39161 6	25mg	R-00473	07-2019		
0904-6390-61 3 09046 39061 9	50mg	R-00498	08-2019		
		R-00568	10-2019		
0904-6389-61 3 09046 38961 3	100mg	R00759D	06-2020		