



URGENT: DRUG RECALL

January 10, 2019

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 style="padding: 2px;">Losartan Potassium Tablets, USP 50mg</td> <td style="text-align: center; padding: 2px;">0904-6390-61</td> <td style="text-align: center; padding: 2px;">10 x 10 Unit Dose</td> <td style="text-align: center; padding: 2px;">R-00474</td> <td style="text-align: center; padding: 2px;">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: Torrent Pharmaceuticals Ltd. Bharuch-392160, India</p>	Product	NDC Number	Size	Lot Number	Expiry Date	Losartan Potassium Tablets, USP 50mg	0904-6390-61	10 x 10 Unit Dose	R-00474	07-2019
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Losartan Potassium Tablets, USP 50mg	0904-6390-61	10 x 10 Unit Dose	R-00474	07-2019							
REASON	<p>We have been informed by Torrent Pharmaceuticals Limited that they are voluntarily recalling the product 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-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution and industrial processes and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification."</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 1-877-274-7163 or email to harvarddrug10034@stericycle.com. 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <ul style="list-style-type: none"> Stericycle, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 10034 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 09/16/2017 and 02/01/2018.</p> <p>For questions regarding returns, please contact Stericycle at 1-877-220-4728. 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>April 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

January 10, 2019

Product: Losartan Potassium Tablets, USP 50mg
Affected NDC Number: 0904-6390-61
Affected Lot Number: R-00474
Exp. Date: 07-2019
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: 1-877-274-7163**
Email: harvarddrug10034@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, USP 50mg

NDC / UPC Number	Lot Number	Expiration Date	Whole Units on Hand	Partial Units on Hand
0904-6390-61 3 09046 39061 9	R-00474	07-2019		