

RANBAXY

RANBAXY PHARMACEUTICALS INC., 9431 FLORIDA MINING BLVD. EAST, JACKSONVILLE, FL 32257. PHONE: (904) 470-6000 FAX: (904) 880-9645

January 16, 2014

URGENT: DRUG RECALL

**RE: Atorvastatin Calcium Tablets, 10mg
(Lot # 2407255 and 2407256, Expiry date: May, 2014 for both the lots)
(NDC: 63304-827-90)**

Dear Valued Customer,

This is to inform you of a product recall being conducted voluntarily by Ranbaxy for Atorvastatin Calcium Tablets, 10mg. The subject lots of Atorvastatin Calcium Tablets, 10 mg were manufactured by Ranbaxy at its facility, A-41, Mohali, Punjab, India.

In August 2012, Ranbaxy had initiated a recall of a lot of Atorvastatin tablets 10 mg, based on receipt of a product complaint wherein an Atorvastatin 20 mg tablet was discovered by a pharmacist in a 90 count bottle of Atorvastatin 10 mg tablets. During a subsequent review of that market complaint and associated investigations, two other Atorvastatin 10 mg lots (2407255 and 2407256 – both packaged in 90s count bottles) have been identified wherein there could be a possibility of an Atorvastatin 20 mg tablet(s) getting packaged in these bottle packs. Till date, we have not received any such complaint for these lots, which will expire in May 2014. However, keeping the health and safety of our customers in mind, Ranbaxy has decided to voluntarily recall these two lots of Atorvastatin Calcium Tablets, 10mg (Lot# 2407255 and 2407256) which were packaged entirely in 90's count bottles.

This recall is being carried out to the retail level and is being conducted with the full knowledge of the FDA.

Please examine your inventory and quarantine any product pertaining to:

| Product, Lot#/Ranbaxy's Lot Distribution dates | Strength | Size | NDC # |
|---|-----------------|-------------|--------------|
| Atorvastatin Calcium Tablets, 10mg Lot # 2407255 Distribution start date: 6/27/12 Distribution end date: 8/30/12 | 10 mg | 90 counts | 63304-827-90 |
| Atorvastatin Calcium Tablets, 10mg Lot # 2407256 Distribution start date: 7/2/12 Distribution end date: 7/31/12 | 10 mg | 90 counts | 63304-827-90 |

In addition, please identify all your customers down to the retail level that this product may have been distributed to and notify them at once of this product recall. Based on FDA's requirement, we will need you to send us a copy of the notification that you provide to your customers down to the retail level, along with a list of customers notified of the recall.

We request that you take the following action steps:

1. Immediately cease distribution of the drug product from the affected lot and remove it from active inventory.
2. If you have any product from the affected lot, please contact our Recall Coordinator:

Heather Itani
C/o Ranbaxy Pharmaceuticals Inc.
Ranbaxy Returns Dept.
Phone: 904-470-6028
Fax: 904-880-9645
heather.itani@ranbaxy.com

and promptly return the attached "Recall Response Form" to her at the above fax number or email address for issuance of a Return Authorization (RA) Form. Upon receiving the RA Form, please return all Atorvastatin Calcium Tablets, 10mg of Lot # 2407255 and 2407256 (expiry for both lots May 2014) via expedited carrier to:

RETURN GOODS DEPT.
c/o Ranbaxy Pharmaceuticals Inc.
9431 Florida Mining Blvd. E.
Jacksonville, Florida 32257

OR


MED-TURN, INC. (f/k/a CAROLINA LOGISTICS; also f/k/a USF PROCESSORS)
4332 Empire Road, Fort Worth, TX 76155
PH: 817-868-5300, 800-967-5952
RA REQUEST FAX LINE: 817-868-5343
E-MAIL: RECALLNOTICE@INMAR.COM , DEA # RR0191902

3. Credit for any returned merchandise, along with shipping charges, will be reimbursed by credit memo.

If you have any further questions other than on the above point #2, please feel free to contact me at 904-470-6034 or at blynda.masters@ranbaxy.com. Our primary concern is always for the health and safety of our customers and this recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your cooperation and sincerely regret any inconvenience caused by this action.

Best Regards,


Blynda B. Masters

Director Customer Service &
Contracts/Chargebacks

RECALL RESPONSE FORM

RE: Atorvastatin Calcium Tablets, 10mg
(Lot # 2407255 and 2407256, Expiry date: May, 2014 for both lots)
(NDC: 63304-827-90)

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the January 16, 2014 Recall Letter.

☐ I have checked my stock and have quarantined inventory consisting of :

| # of units | Product, Lot#/Ranbaxy's Lot Distribution dates | Strength | Size | NDC # |
|------------|---|----------|-----------|--------------|
| | Atorvastatin Calcium Tablets, 10mg Lot # 2407255 Distribution start date: 6/27/12 Distribution end date: 8/30/12 | 10 mg | 90 counts | 63304-827-90 |
| | Atorvastatin Calcium Tablets, 10mg Lot # 2407256 Distribution start date: 7/2/12 Distribution end date: 7/31/12 | 10 mg | 90 counts | 63304-827-90 |

☐ Please check the appropriate box (es) to describe your business

- | | |
|---|--|
| <input type="checkbox"/> Wholesaler/distributor | <input type="checkbox"/> retailer |
| <input type="checkbox"/> Grocery corporate headquarters | <input type="checkbox"/> hospital pharmacies |
| <input type="checkbox"/> Repackager | <input type="checkbox"/> medical laboratory |
| <input type="checkbox"/> Pharmacy – retail | <input type="checkbox"/> hospital/medical facility |
| <input type="checkbox"/> Other: _____ | |

- ☐ I have notified my retail level/wholesaler customers of this recall
- ☐ Yes (provide copy of the letter/notification, and list of customers notified)
- ☐ No

Name: _____

Title: _____

Email: _____

Tel. number: (____) _____

Fax number: (____) _____

Company name: _____

Address: _____

City/State/Zip: _____

PLEASE FAX COMPLETED RESPONSE FORM TO:

904-880-9645

ATTN: Heather Itani

RETURNED GOODS

You may also email to: heather.itani@ranbaxy.com

OR MAIL TO:

Ranbaxy Pharmaceuticals Inc.

9431 Florida Mining Blvd. East

Jacksonville, Florida 32256

ATTENTION: RETURNED GOODS