URGENT: ACTOPLUS MET XR 15 MG/1000 MG DRUG RECALL

September 10, 2018

Site Quality
Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015

Dear Valued Customer:

This is to inform you of a product recall involving:

> PIOGLITAZONE AND METFORMIN HYDROCHLORIDE EXTENDED-RELEASE, ACTOPLUS MET XR, 15 MG/1000 MG TABLETS FOR ORAL USE, NDC NUMBER 64764-510-30, LOT NUMBERS A26004, A26443, A26444

See enclosed product label for ease in identifying the product at retail level.

This recall has been initiated due to a potential defect of tablets missing, in whole or in part, the laser drilled holes on the metformin core of the Actoplus met XR tablets. Ingestion of a tablet from these lots does not pose a risk to patients of adverse events when compared to ingestion of a tablet containing both laser drilled holes. Use of tablets missing these holes may result in a Lack of Effect (LOE) and patients should not attempt to compensate for this defect by ingesting additional tablets.

Takeda Pharmaceuticals U.S.A., Inc. began shipping these lots to wholesalers on the following dates:

Lot A26004: May 03, 2018
Lot A26443: July 12, 2018
Lot A26444: July 18, 2018

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

If you have any of the recalled lots at your location or if any of the recalled lots are returned to you, please quarantine the product and contact Stericycle, Inc. at 888-603-8990 to receive instructions on returning this product.

This recall should be carried out to the retail level, including any intermediate wholesalers with whom you do business. Your assistance is appreciated and necessary to prevent patients from experiencing a potential LOE with these lots.

Please complete and return the enclosed response form as soon as possible. If you have any questions regarding the return of materials, contact Stericycle, Inc. at 888-603-8990. To report all adverse events or quality problems suspected with the use of Actoplus met XR contact the Takeda Call Center at 877-Takeda-7 (877-825-3327).

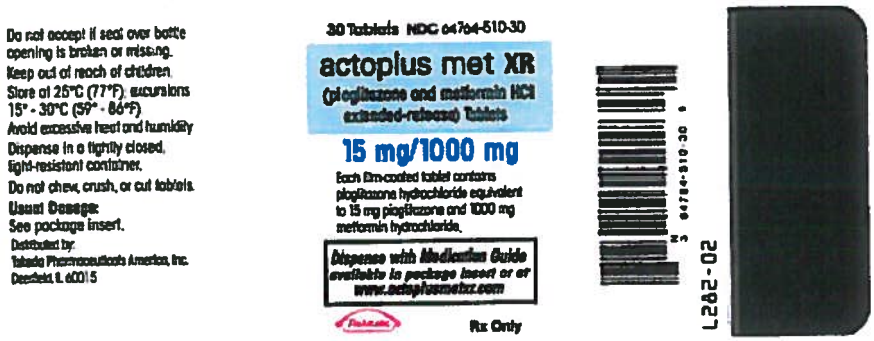
This recall is being made with the knowledge of the Food and Drug Administration.

05Sept 2018

John Margetson
Site Quality Head

Enclosure(s):
Product Labeling

Example of Bottle Label



Example of Bottle – Lot A26004

DRUG RECALL REPLY FORM – RESPONSE REQUIRED
Actoplus met XR 15mg/1000mg
Lot Numbers: A26004, A26443 and A26444

Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the September 10, 2018 letter.
- ☐ I have checked my inventory and have quarantined inventory consisting of (*please complete the following, even if you do not have the affected product*):
  - _____ Sealed Bottles
  - _____ Unsealed Bottles
- ☐ I have initiated the return of all product listed above on _____ (date) via the provided instructions and UPS pre-paid shipping label.
- ☐ I have identified and initiated the notification process to my customers that may have been shipped this product from May 3, 2018 through the present.

Any adverse events associated with recalled product? ☐Yes ☐No
If yes, please explain:

_____
_____

Business Name: _____
Telephone Number: _____
Street Address: _____
City/State/Zip: _____

Completed by:
Printed Name _____
Title _____
Signature _____
Date _____

PLEASE FAX THE COMPLETED RESPONSE FORM TO: (888) 912-8456
OR EMAIL TO: Takeda6335@stericycle.com