Actavis

URGENT DRUG RECALL
January 30, 2017

Actavis Generics, an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

This is to advise you of an Actavis voluntary recall of 12 lots of GLIPIZIDE 2.5 MG ER Tablets, NDC 0591-0900-30 in 100cc bottles with desiccant. The recalled product lots were manufactured by Patheon Cincinnati, OH under the Watson Laboratories, Inc. label. Specific product recall information are given in the sections that follow, which details (1) recalled product information, (2) reason for recall, (3) depth of recall, (4) health hazard, and (5) instructions for returning the affected lots.

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

**RECALLED PRODUCT INFORMATION**

| *Product* | *NDC* | *Packaging* |
|---|---|---|
| GLIPIZIDE 2.5 MG ER Tablets | 0591-0900-30 | 30-Count 100 CC Bottle w/ Desiccant |

| Lot No. | Exp. | Distribution (From - To) | Lot No. | Exp. | Distribution (From - To) |
|---|---|---|---|---|---|
| 3134201 | 06/30/17 | 09/08/2015 - 11/11/2015 | 3136782 | 09/30/17 | 03/09/2016 - 03/31/2016 |
| 3134202 | 06/30/17 | 11/04/2015 - 12/09/2015 | 3136903 | 10/31/17 | 04/07/2016 - 05/19/2016 |
| 3134319 | 05/31/17 | 09/14/2015 - 10/16/2015 | 3136904 | 10/31/17 | 05/10/2016 - 05/11/2016 |
| 3135246 | 07/31/17 | 12/04/2015 - 01/07/2016 | 3138250 | 07/31/17 | 12/21/2015 - 01/07/2016 |
| 3135247 | 08/31/17 | 01/05/2016 - 02/01/2016 | 3138968 | 08/31/17 | 12/30/2015 - 03/22/2016 |
| 3136781 | 08/31/17 | 01/14/2016 - 03/11/2016 | 3140000 | 09/30/17 | 03/14/2016 - 04/26/2016 |

| | |
|---|---|
| **Reason:** | Drug release results for Lot # 3136782 were slightly above specification at one time point. All other time points were within specification. As a precautionary measure, all lots within expiry packaged in 30-Count 100 CC Bottle w/ Desiccant are being recalled. |
| **Depth of Recall:** | *RETAIL* |
| **Health Hazard Evaluation:** | Glipizide is an oral rapid- and short-acting anti-diabetic drug. Rate of drug release determines availability of the drug for absorption. If a tablet releases the drug too quickly, the blood level of the drug may become too high, causing an excessive response (e.g. hypoglycaemia). The use of or exposure to the product may cause temporary or medically reversible adverse health consequences, and the probability of serious adverse health consequences is remote. |

**ACTIONS REQUIRED**

Upon receipt of this letter, please take the following actions:

1. Stop distribution and quarantine the specified recalled lot numbers.
2. *If you have further distributed the recalled lot numbers, please notify your customers of this recall to the RETAIL level and to follow the instructions given here for responding and for returning the recalled product.*
3. Carry out a physical count of the specified recalled lot numbers and record the amount(s) on the enclosed postage paid Business Reply Form (BRF) and Packing slip.
4. *Even if you do not have the recalled product in your inventory,* mail the postage paid BRF within five (5) business days. To assure that we can account for all customers it is *imperative that you return the BRF even if you do not have product in stock*.
5. Attach the prepaid *FedEx* Authorized Return shipping label to the outside of the return carton. Return the recalled product and completed Packing Slip to:

   GENCO Pharmaceutical Services, a subsidiary of FedEx Supply Chain, 6101 North 64th Street, Milwaukee, WI 53218

***Please contact GENCO if these recall actions are unclear or to obtain BRF, Packing Slip, & Return Shipping Label.***

**CONTACT INFORMATION AND CREDIT**

| Product Returns | Medical Inquiries/ Adverse Events/Product Complaints | Reimbursements |
|---|---|---|
| Contact GENCO at: | Contact Actavis at: | Contact Actavis at: |
| 855-633-1429 | 800-432-8534 | 973-265-3533 |
| 7 am - 5 pm CST | 8am – 5pm EST | 9am – 5pm EST |

FDA contact information for reporting adverse events/quality complaints:
Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Credit will be issued only for product that you return that is associated with this recall. All product received in response to this recall, which is not associated with this recall, will be destroyed and credit will not be issued.

**We appreciate your cooperation in this product recall, and regret any inconvenience that this may have caused. Thank you for your assistance in this matter.**

Sincerely,

Actavis Generics, an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.