

URGENT: DRUG RECALL

**HRS Lot All lot numbers beginning with the letter “K”
Example K12345**

Repackaged by:
Heartland Repack Services
Toledo, Ohio

Recalled by:
Heartland Repack Services
Toledo, Ohio

Dear Customer,

Heartland Repack Services is voluntarily recalling all products containing a lot number beginning with “K”. The specific products and lot numbers subject to this recall can be found on the attached list. These product lots are distributed from Heartland Repack Services in 30, 60, 90 count size boxes and 250 count bags. Both the boxes and bags contain unit dose strips of five tablets per strip.

See attached list for specific products.

Only products with a lot number beginning with the letter “K” are subject to this recall. Products containing lot numbers which begin with any other letter or number are not subject to this recall and should not be returned. This recall was initiated because there is the potential for packaging mix-up.

Please inspect your entire inventory for any of the affected products. If you have of these recalled lots, immediately discontinue use, quarantine the product and return to Heartland Repack Services per the instructions contained in this letter.

This recall is being conducted to the **patient level**.

Upon Receipt of this letter, take the following actions:

1. This recall extends to the **patient level**. Immediately examine your inventory to include boxes and bags and if you have any of the recalled lots in stock, quarantine and discontinue dispensing the product.
2. Complete the enclosed RECALL NOTICE ACKNOWLEDGEMENT immediately, and fax it back to Joyce Gregory (Fax #419-537-8364).
3. **Please ensure you contact each facility** that you have dispensed product with a “K” lot number to and have any product returned directly to your facility.

4. Complete and fax or mail the enclosed RECALL STOCK RESPONSE to Heartland Repack Services after you have determined whether any remaining stock is subject to this recall and after receiving stock back from your facilities. Include a copy of the RECALL STOCK RESPONSE in your return.
5. When all products are returned to your pharmacy, consolidate and return to Heartland Repack Services.
6. All product is to be returned to:

Heartland Repack Services LLC
302 S. Byrne
Toledo, Ohio 43615
Attn: Joyce Gregory

Please use RA # 1007486 to return the product. Recalled product returned without referencing the above RA# and a copy of the RECALL STOCK RESPONSE may delay the issuance of your credit.

7. As soon as your return shipment is processed, a credit will be issued for the value of the merchandise, plus shipping costs.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response is much appreciated. If you have questions, please contact Stephen Dauss at 800-270-6351 ext 6022.

Regards,

Stephen Dauss
Director Quality Assurance
Heartland Repack Services LLC

cc: Denis Holmes, Ralph Breitfeller, Cheryl Iossi, and Joyce Gregory