

Digitek Recall

On April 25, 2008, the U.S. Food and Drug Administration (FDA) advised that Actavis Totowa LLC was initiating a Class I nationwide recall of Digitek® (digoxin tablets, USP, all strengths) for oral use. These products are distributed by Mylan Pharmaceuticals Inc., under a “Bertek” label and by UDL Laboratories, Inc. under a “UDL” label.

This product is being recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than appropriate. Double strength tablets could pose a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received.

All pharmacies that have this product in stock are urged to return the product to the place of purchase.

What does this mean to you?

1. CIGNA HealthCare has removed the Digitek® NDCs from our claims system to prevent any further processing of the recalled products.
2. We are identifying all CIGNA HealthCare and CIGNA MedicareRx members impacted by this recall and are entering refill-too-soon authorizations to allow the processing of Digoxin from other manufacturers.

We ask that you follow your standard emergency fill guidelines. If you need further assistance with processing a claim, please contact our CIGNA Pharmacy Help Desk at 1-800-558-9363. For additional information about this voluntary recall, you may visit www.actavis.us or click this link to the FDA website http://www.fda.gov/oc/po/firmrecalls/actavis04_08.html.

If you have any questions, please contact me by phone at 860-226-5837 or e-mail at Karen.Stober@CIGNA.com.

Thank you,

Karen Stober

CIGNA does not take responsibility for any medication decisions made by prescriber and pharmacist.

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