

Urgent: Drug Recall

Digitek® (digoxin tablets, USP)

Recall initiated by the manufacturer: Actavis Totowa LLC (formerly known as Amide Pharmaceuticals, Inc.)

Product Distributed by: Mylan Pharmaceuticals, Inc. under a "Bertek" Label

PRODUCT	NDC	Name	Strength	Size	Lot #
	62794-145-01	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 100s	All lots
	62794-145-10	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 1000s	All lots
	62794-145-56	Digitek® (Digoxin Tablets, USP)	125 mcg (0.125 mg)	Bottles of 5000s	All lots
	62794-146-01	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 100s	All lots
	62794-146-10	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 1000s	All lots
	62794-146-56	Digitek® (Digoxin Tablets, USP)	250 mcg (0.25 mg)	Bottles of 5000s	All lots

REASON

Mylan Pharmaceuticals Inc. is continuing a voluntary recall of the Actavis Totowa recall of Digitek® (digoxin tablets, USP). 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 is appropriate. Product was distributed nationwide between March 2006 and April 2008.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses 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 by Actavis.

ACTION

1. Immediately examine your inventory and quarantine and discontinue distribution of all lots within expiry.
2. In addition, if you may have further distributed the recalled product, please identify your retail-level customers and notify them at once of this product recall.
3. Additionally, if the retail-level customers have further distributed the recalled product, please identify the consumer and notify them immediately of this product recall. They should instruct the consumer to contact Stericycle at 1-888-276-6166 for the return of the product.
4. Consumers should discuss their treatment options and change in therapy with their physician.
5. Carry out a physical count and record this data on the Business Reply Card and the Packing Slip which are included with this letter. Federal Regulations require a physical count.
6. Mail the postage paid Business Reply Card to the address provided. Federal regulations require that you return this completed card even if you do not have the recalled product.
7. Return the recalled product with the Packing Slip using the prepaid UPS RS shipping label to:
Stericycle
2670 Executive Drive, Suite A
Indianapolis, IN 46241

OTHER

This recall extends to the consumer level.

Credit/check will be issued for return of recalled product.

Any other product returned that is not involved with this recall will be destroyed and credit will not be issued.

For questions regarding Digitek® Tablets (digoxin tablets, USP) recall, please call Stericycle at 1-888-276-6166.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.