



## RECALL INFORMATION

### Digitek Class 1 Recall

**April 30, 2008** - On Monday, April 28, Actavis Totowa LLC notified health care professionals of a Class I nationwide recall of all strengths of Digitek. The products are distributed by Mylan Pharmaceuticals Inc. under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label. The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. 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. Several reports of illnesses and injuries have been reported.

The FDA defines a Class I Drug Recall as a situation in which there is reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

#### Recall Procedure

The FDA and manufacturer urge pharmacies to return the recalled product to their place of purchase (wholesaler). Pharmacies should follow instructions they receive from their wholesaler in order to return product. Patients are urged to consult health care providers with questions. According to the FDA and the Wisconsin PEB, there is "no explicit duty" for pharmacists to proactively obtain previously dispensed product from patients. PSW however, has provided members with suggested options and "best practices" for [handling a Class I Drug Recall](#). These suggestions were developed by the Wisconsin Pharmacy Quality Collaborative (WPQC) to address the quality-based network requirement that WPQC pharmacies must have a policy in place to "establish and maintain standards for communicating and executing Class I Drug Recalls and necessary actions pertaining to FDA Drug Safety Alerts."

PSW members have reported that some physicians have recommended patients get a digoxin level drawn.

#### Drug Shortage Information

Estimated Resupply Dates from [ASHP Website](#)

- Digitek from Mylan Bertek and UDL is unavailable and the companies cannot estimate a return date
- Lannett's products are on back order and the company cannot estimate a release date
- Westward will release all presentations mid-May, 2008
- Caraco has all presentations of digoxin 0.125 mg and 0.25 mg tablets available
- GlaxoSmithKline has all presentations of Lanoxin 0.125 mg and 0.25 mg tablets available

#### Billing Information

DHFS (Medicaid/BadgerCare/SeniorCare) has instructed EDS to remove the MAC and Brand Medically Necessary (BMN) requirements on digoxin products. DHFS is asking that providers dispense the drug. EDS has confirmed that billing details will be corrected by Friday, May 2 when providers will be able to bill and be reimbursed the AWP-13% + dispensing fee. The brand will be available without restrictions. Providers that have trouble billing Medicaid for digoxin products after Friday, May 2 are instructed to contact Sue Halfmann at (608) 266-1203 and she will work with EDS to ensure the proper changes have been made.

**Links**

More information on the [Digitek Recall](#) is available from the FDA.

The manufacturers [press release](#) is also available.

Please contact the PSW Offices at (608) 827-9200 with additional questions.