

## Recall on Heart Failure Medication, Digitek®

*Digitek®  
double-  
strength  
tablets may  
lead to  
nausea,  
vomiting,  
dizziness,  
low blood  
pressure,  
cardiac  
instability  
and  
bradycardia.*

Actavis Totowa, LLC manufacturer of Digitek® (digoxin tablets, USP, all strengths), a medication used to treat heart failure and abnormal heart rhythms is initiating a Class I nationwide recall of all strengths of the product. The FDA defines a Class I recall as a reasonable probability that the use of or exposure to a violative product (i.e. Digitek) will cause serious adverse health consequences or death. Digitek is distributed by Mylan Pharmaceuticals, Inc. under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary recall on Digitek is being conducted 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. Patients should contact their healthcare professional with inquiries.

All Digitek claims will no longer be processed by Benecard's claim processor due to the recall. All NDC numbers that identify Digitek products have been removed from our system. This procedure will remain in place until further notice. However, Benecard will approve dispensing for an alternative form of digoxin produced by a different manufacturer. This alternative form will have the same active ingredient and strength as the recalled medication.

We encourage you to share this information with your clients and their cardmembers.

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