

Actavis announces nationwide recall of Digitek® (digoxin)

On April 25, 2008, Actavis Totowa LLC initiated a Class I voluntary recall of Digitek (digoxin), all lots and strengths of oral tablets. In a Class I recall, the manufacturer completely removes a product from the marketplace because exposure to the drug will cause serious adverse health consequences or death.

Digitek is used to treat heart failure and abnormal heart rhythms. It is manufactured by Actavis Totowa and distributed by Mylan Pharmaceuticals Inc. and by UDL Laboratories, Inc.

The recall stems from the possibility that some tablets may contain twice the approved amount of digoxin. Double-strength tablets may pose a risk of digitalis toxicity in patients with kidney failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, and irregular or slow heartbeats. Death can also result from excessive digoxin intake. Several reports of illnesses and injuries have been received.

Members currently taking Digitek are advised to contact their doctor immediately to discuss appropriate alternative treatments. Other generic and brand alternatives to Digitek are available on the market. Any decision about which medication to take should be made by the physician based on individual patient needs.

According to Actavis, any customer inquiries related to this action should be addressed to Stericycle Customer Service at 1-888-276-6166 with representatives available Monday through Friday, 8 a.m. to 5 p.m. EST. Additional information about the voluntary recall can be found at www.actavis.us.

References:

1. Food and Drug Administration website. Available at www.fda.gov. Viewed April 28, 2008.