

URGENT! EMERGING THERAPEUTIC ISSUES COMMUNICATION

Actavis has announced a voluntary nationwide recall of all lots and strengths of Digitek® (digoxin) tablets. Actavis manufactures Digitek, which is distributed under the Bertek and UDL labels. This recall is being conducted due to a possibility that tablets with double the appropriate thickness (and double the dose) have been distributed. Digitek tablets are used to treat heart failure and abnormal heart rhythms. Double-strength tablets could increase the risk of digitalis toxicity, especially in patients with kidney failure. Symptoms of digitalis toxicity include: nausea, vomiting, dizziness, low blood pressure and decreased heart rate. Death can also occur.

Any questions regarding this recall should be directed to Stericycle customer service at 1-888-276-6166. Additional information about the voluntary recall can be found at www.actavis.us. FDA's MedWatch website at: www.fda.gov/medwatch/safety.htm. You can also call FDA at 1-888-INFO-FDA (automated) or 301-827-4570.

Express Scripts response:

- In an effort to inform members of this recall, we have identified members who have received a prescription for Digitek tablets labeled within the past 120 days. A communication summarizing the information provided by the manufacturers will be sent to these members.
- A physician communication will also be distributed, along with patient profiles. This information is intended to help them identify current Digitek users that will need to be switched to digoxin tablets (0.125mg or 0.25mg) that are distributed by another manufacturer. There are several other companies that supply generic digoxin tablets. The brand product, Lanoxin®, is manufactured by GlaxoSmithKline.
- The above communications will be distributed for those clients enrolled in the member and physician portions of the Emerging Therapeutic Issues Patient Safety Program., respectively.

If we can answer any questions, or if you are interested in the Emerging Therapeutic Issues Program and are currently not enrolled, please contact your Clinical Program Manager at your convenience.