

Drug Alert

Important Drug Information



May 15, 2009

Dear Client,

The HealthTrans clinical team works proactively to provide you with important FDA drug alerts as they are released. With your best interest in mind, we monitor all relevant changes to the status of drugs to ensure that you are well informed of issues that may affect your prescription benefit and members' overall health. We recommend that you share this information within your setting as appropriate.

Nationwide Recall of All Lots of Digoxin Tablets 0.25mg Due to Size Variability

A S Medication Solutions, LLC, a drug repackage company, announced today that all tablets of Caraco brand Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of August, 2011, are being voluntarily recalled to the consumer level. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. Caraco Pharmaceutical Laboratories, Ltd manufactured the recalled tablets. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Digoxin is a drug product used to treat heart failure and abnormal heart rhythms. It has a narrow therapeutic index and the existence of higher than labeled dose may pose a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability, and slow heart rate. Death can also result from excessive digoxin intake. A lower than labeled dose may pose a risk of heart failure and abnormal heart rhythms.. Consequently, as a precautionary measure, A S Medication Solutions, LLC is recalling these tablets to the consumer level to minimize any potential risk to patients.

Consumers with the products with the following NDC codes that are within expiration should return these products to the place of purchase.

NDC Numbers:

Digoxin Tablets, USP, 0.25 mg
54569-5758-0 (30-count)

Patients using A-S Medication Solutions, Digoxin tablets, USP, 0.25 mg, who have medical questions should contact their healthcare provider for additional instructions or guidance.

Healthcare providers who have this product should return the product to their place of purchase. Healthcare providers can call A-S Medication Solutions Recall Coordinator at (847) 680-3515, Monday through Friday, 8:00 a.m. – 4:00 p.m. CST, for instructions on how to return the affected product or for any other inquiries related to this action.

Any adverse reactions experienced with the use of all affected product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at Med Watch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Thank you for your attention to this important message.