

Caraco Pharmaceutical Laboratories, Ltd. announces nationwide voluntary recall of all lots of digoxin tablets

On March 31, 2009 Caraco Pharmaceutical Laboratories, Ltd. (NYSE Amex: CPD), a generic pharmaceutical company, announced that all tablets of Caraco brand Digoxin, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of September 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. The recalled tablets were manufactured by Caraco Pharmaceutical Laboratories, Ltd. This recall is being conducted with the knowledge of the 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 bradycardia. Death can also result from excessive digoxin intake. A lower than labeled dose may pose a risk of lack of efficacy potentially resulting in cardiac instability. Consequently, as a precautionary measure, Caraco is recalling these tablets to the consumer level to minimize any potential risk to patients.

Affected NDC Numbers:

Digoxin Tablets, USP, 0.125 mg

57664-437-88 (100-count)

57664-437-18 (1000-count)

Digoxin Tablets, USP, 0.25 mg

57664-441-88 (100-count)

57664-441-18 (1000-count)

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

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.

In response to this event, FutureScripts/FutureScripts Secure is:

- Posting a point-of-sale (POS) message to retail pharmacists. Claims submitted for the affected NDCs for these products will reject at the point of sale with the following message: “NDC NOT ON FILE”.
- Overriding refill-too-soon rejections for members needing replacement medications.
- Posting a Web Alert for our members and providers on www.futurescripts.com.

References:

Food and Drug Administration website. Available at www.fda.gov. Accessed March 31, 2009.

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