



Compliance Alert

April 6, 2009

Express Scripts – Two Emerging Therapeutic Issues

#1 Emerging Therapeutic Issue

Watson Corporation has announced a voluntary recall of one lot of its propafenone HCl 225mg tablets. The recalled lot (#112680A) was distributed between October 15, 2008 and November 26, 2008. These tablets are being recalled because of a chance that the lot contains oversized tablets that contain slightly higher levels of drug than specified. Propafenone is used to treat irregular heartbeats. Small variation in doses may result in potentially serious side effects, including arrhythmias (irregular heartbeat) or low blood pressure. Consequently, as a precautionary measure, Watson is recalling this lot to the consumer level to minimize any potential risk to patients.

According to the manufacturer, anyone with 225 mg propafenone HCL tablets being recalled should call (888) 352-9616, Monday through Friday, 8 a.m. to 5 p.m. EDT, for instructions on how to return the affected product. Additional information can be found on FDA's MedWatch website at: www.fda.gov/medwatch/safety.htm. You can also call FDA at 1.888.INFO.FDA (automated) or (301) 796-3400.

Express Scripts response:

- In an effort to inform members of this recall, we have identified members who have received a prescription for propafenone HCl 225mg tablets manufactured by Watson within the past 120 days. A communication summarizing the information provided by the manufacturer will be sent to these members.
- The above communications will be distributed for those clients enrolled in the member portion of the Emerging Therapeutic Issues Patient Safety Program.

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#2 Emerging Therapeutic Issue

Caraco Pharmaceutical Laboratories has announced a voluntary recall of all of its digoxin 0.125mg and 0.25mg tablets, distributed prior to March 31, 2009, which are not expired and are within the expiration date of September 2011. These tablets are being recalled because they may differ in size and could contain more or less of the drug than specified. Digoxin is a narrow therapeutic index drug used to treat heart failure and abnormal heart rhythms. A higher than intended dose can result in digoxin toxicity patients with kidney failure. Digoxin toxicity can also result in other side effects including nausea and vomiting, low blood pressure, decreased heart rate, cardiac instability and death. A lower than intended dose can also result in cardiac instability. Consequently, as a precautionary measure, Caraco is recalling this lot to the consumer level to minimize any potential risk to patients.

According to the manufacturer, anyone with digoxin 0.125mg or 0.25mg tablets that are within the expiration date should return these products to the pharmacy where the drug was purchased. Pharmacies should call (800) 818-4555, Monday through Friday, 8 a.m. to 5 p.m. EDT, for instructions on how to return the affected product. Additional information can be found on FDA's MedWatch website at: www.fda.gov/medwatch. You can also call FDA at 1.888.INFO.FDA (automated) or (301) 796-3400.

Express Scripts response:

- In an effort to inform members of this recall, we have identified members who have received a prescription for digoxin 0.125mg and 0.25mg tablets manufactured by Caraco within the past 120 days. A communication summarizing the information provided by the manufacturer will be sent to these members.
- The above communications will be distributed for those clients enrolled in the member portion of the Emerging Therapeutic Issues Patient Safety Program.

If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.

This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.

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