



# Compliance Alert

June 5, 2008

## **Express Scripts – Urgent – Two Emerging Therapeutic Issues**

### **Therapeutic Issue # 1**

On May 6, 2008, a truck containing Johnson & Johnson's Remicade<sup>®</sup> (infliximab), Procrit<sup>®</sup> (epoetin alfa) and Doxil<sup>®</sup> (doxorubicin liposomal inj.) was stolen. The company is recalling these products due to concerns the supply could be reintroduced into the market and its safety can no longer be assured. As a precaution, the company is taking all lots of Remicade, Procrit and Doxil with the same lot numbers as the stolen products off of the market. This will make it easier to identify the stolen drug if it does reenter the market. All other lots are considered safe to use.

Of the stolen drugs, only Procrit is self administered. The recalled lots of Procrit include:

<u>Drug</u>	<u>Lot Number</u>	<u>Expiration Date</u>
Procrit (10,000 U/ml) single use vials	D091534	07/2010
Procrit (20, 000 U/ml) multidose vials	P113612	09/2010
Procrit (40,000 U/ml) single use vials	P106803	06/2010

More information can be found at:

[http://www.procrit.com/procrit/assets/PR\\_15MAY2008.pdf](http://www.procrit.com/procrit/assets/PR_15MAY2008.pdf)

### **Express Scripts response:**

- In an effort to inform members of this recall, we have identified members who have received a prescription for Procrit since May 7, 2008. A communication summarizing the information provided by the manufacturers will be sent to these members.
- 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.

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## **Therapeutic Issue # 2**

Medicis has announced a voluntary nationwide recall of two lots of Solodyn<sup>®</sup> (minocycline) Extended-Release Tablets, 90mg [Bo80037 (Exp: 12/09) and B080038 (Exp: 12/09)]. AAI Pharma manufactures Solodyn through a contract agreement with Medicis. This recall is being conducted because Medicis has received a report that one bottle in lot number B080037 contains Azasan<sup>®</sup> (azathioprine) 75mg tablets instead of Solodyn. Solodyn is an antibiotic used to treat acne while Azasan is an immunosuppressant used to prevent kidney rejection in transplant patients and rheumatoid arthritis. Taking Azasan can result in side effects including: myelosuppression (decreased red blood cells, white blood cells, and platelets), infection, bleeding, chills, nausea, vomiting, diarrhea as well as joint and muscle pain.

Any questions regarding this recall should be directed to Stericycle customer service at 1-888-656-6381. Additional information about the recall can be found at [www.solodyn.com](http://www.solodyn.com) and FDA's MedWatch website at [www.fda.gov/medwatch/safety.htm](http://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 Solodyn tablets labeled within the past 120 days. A communication summarizing the information provided by the manufacturers will be sent to these members.
- 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 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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