

Compliance Alert

July 25, 2006

Compliance Alert, provided by Group Benefit Services, gives you the most up to date information regarding industry news as well as legislation and regulatory activities affecting your health plan.

TOPIC: EMERGING THERAPEUTIC ISSUE FROM ESI

Recently, Roxane Laboratories, the maker of generic azathioprine 50mg tablets, announced a recall of a single lot number (Lot 558470A; NDC#: 00054-4084-25) because a single bottle has been identified as containing methotrexate 2.5mg tablets. While it is believed that this issue may be limited to this single bottle, the decision was made to recall the entire lot number to prevent any possibility of another such bottle being distributed or used.

According to the manufacturer, if methotrexate 2.5mg tablets are taken in place of azathioprine 50mg tablets in accordance with dosing instructions that may be prescribed for azathioprine, serious toxic effects may occur, including a decreased resistance to infection, mouth ulcers, reduced blood counts, vomiting, diarrhea, liver, kidney or lung injury. There have also been reports of death at high doses of methotrexate, such as might result from a substitution of methotrexate 2.5mg tablets for azathioprine 50mg tablets.

The manufacturer is recommending that patients who have azathioprine 50mg tablets from Roxane should visually inspect their supplies to ensure that they have the correct product. If the tablets are marked with number "54 232", the patient should immediately contact their pharmacist or physician.

If you have any additional questions or would like additional information, please contact Roxane Laboratories Technical Product Information at 800-962-8364.\

Express Scripts response:

- In an effort to inform patients of this notification, we have identified patients who may have received a prescription for azathioprine 50mg tablets from Roxane Laboratories since the first affected lot number was distributed on May 5, 2006. We will send a communication to these patients, summarizing the information provided by Roxane Laboratories.

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- The above communication will only be distributed for those clients enrolled in the patient mailing portion of the Emerging Therapeutic Issues Program.

- Express Scripts Mail Service Pharmacies have notified members serviced out of the Albuquerque and Tempe mail facilities impacted by this recall. No other Express Scripts pharmacies were impacted.

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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