



Compliance Alert

October 29, 2009

Express Scripts – Urgent –Emerging Therapeutic Issues Communication

American Regent has announced a voluntary recall of all lots of its Ketorolac Tromethamine Injection 30 mg/mL, 1 mL and 2 mL single dose vials. The vials are being recalled because particulate matter in conjunction with crystallization may be present in the product. Ketorolac Tromethamine Injection is a non-steroidal anti-inflammatory drug (NSAID) that is administered intravenously or intramuscularly for the short-term treatment of pain. Particulate matter in these vials could potentially obstruct blood vessels, which could induce blood clots to form in the lungs and other parts of the body. Injected particulates could also activate certain blood cells and induce anaphylactic reactions. Less serious adverse effects such as irritation at the injection site could also occur. Consequently, as a precautionary measure, American Regent is recalling this product to the consumer level to minimize any potential risk to patients.

Anyone with this product should not use it and contact their pharmacy where the drug was purchased. Pharmacies should call 1-800-645-1706, Monday through Friday from 8:30 AM to 7:00 PM ET, 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 Ketorolac Tromethamine Injection 30 mg/mL in 1mL or 2 mL single-dose vials manufactured by American Regent within the past 120 days. A communication summarizing the information provided by the manufacturer will be sent to these members.
- The above communication will be distributed for those clients enrolled in the member portion of the Emerging Therapeutics Intervention 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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