

May 3, 2011

**FDA Safety Announcement: Coumadin (warfarin sodium) Crystalline 5 mg Tablets: Recall - Tablets May Have Higher than Expected Potency**



**AUDIENCE:** Cardiology, Pharmacy, Patients

**ISSUE:** Bristol-Myers Squibb has initiated a voluntary recall of one lot of 1,000-count bottles of Coumadin (warfarin sodium) Crystalline 5 mg tablets. Company product testing indicated that a tablet in this lot had a higher potency than anticipated. The affected lot number in the U.S. is **9H49374A** with an expiration date of September 30, 2012. Any decrease of active ingredient in the medication may increase the risk of clots which could lead to heart attack or stroke, and alternatively, if there is too much active ingredient, there is an increased risk of bleeding.

**BACKGROUND:** Coumadin is prescribed to treat and/or prevent blood clots.

**RECOMMENDATION:** It is recommended that patients who may have 5 mg tablets should not interrupt their therapy but should seek advice from their pharmacist to see if they have tablets originating from the affected lot and if so, should consult their physician for additional medical advice.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

In addition, healthcare professionals and customers may call the following number for assistance if they have further questions about the recall:

For information related to this recall:

**Stericycle, Inc.**  
**1-866-918-8739**

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm253615.htm>

[www.kcercoalition.com/alerts.htm](http://www.kcercoalition.com/alerts.htm)