

May 3, 2011

Coumadin (warfarin sodium) Recall

ISSUE: Bristol-Myers Squibb initiated a voluntary recall of one lot of 1,000-count bottles of Coumadin (warfarin sodium) Crystalline 5 mg tablets. Company testing of tablets from a returned bottle found a tablet to be higher in potency than expected. The lot number affected in the U.S. is 9H49374A with an expiry date of September 30, 2012. A decrease of active ingredient may increase the risk of clots which could lead to heart attack or stroke, and if there is too much active ingredient, there is an increased risk of bleeding.

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

RECOMMENDATION: 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 appropriate medical advice.

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

- Complete and submit the report Online: 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