

COUMADIN® Tablets (Warfarin Sodium Tablets, USP) Crystalline, 5 mg

Bristol-Myers Squibb Company has initiated a voluntary recall of one manufactured lot of COUMADIN 5 mg tablets. The lot number affected is 9H49374A, was manufactured in September 2009 and has an expiry date of September 30, 2012. This recall is a precautionary measure based on the Company's testing of tablets from a returned bottle in which a single tablet was found to be higher in potency than expected. Additional tablets from lot 9H49374A were tested and found to be satisfactory. Bristol-Myers Squibb has notified the U.S. Food and Drug Administration (FDA) and is issuing recall communications to all healthcare professionals and other customers involved.

COUMADIN is prescribed to treat or prevent blood clots. If there is too much active ingredient, there may be an increased risk of bleeding. If there is a decrease of active ingredient, there may be an increase in the risk of clots which could lead to heart attack or stroke. A global safety assessment was conducted to evaluate a potential lack of efficacy and no unexpected patterns were identified.

Bristol-Myers Squibb has contracted with a recall vendor, Stericycle (1-866-918-8739), to coordinate all returns of affected product and provide information about reimbursement.

As patients become aware of this recall they may choose to contact their healthcare providers, pharmacists or Stericycle to inquire if their COUMADIN 5 mg tablets are from the affected lot and to seek medical advice.

The following instructions have been provided to patients and consumers via multiple communication channels, including a press release and the Bristol-Myers Squibb Company website.

- Patients who may have COUMADIN 5 mg tablets should not interrupt their therapy, but they should consult their healthcare providers for appropriate medical advice.
- Patients or consumers who have been notified regarding this recall of COUMADIN 5 mg tablets (lot 9H49374A) or who have questions may contact Stericycle at 1-866-918-8739 to obtain additional information and a kit for return of the product.
- Patients or consumers who are unsure if they have tablets from lot 9H49374A have been instructed to contact their dispensing pharmacy for additional information.

The following instructions have been provided to retail and hospital pharmacies:

- Retail and hospital pharmacies that track lot numbers dispensed to patients, should contact patients that have received lot 9H49374A, advise them of the recall, and have them contact Stericycle, to obtain additional information and a kit for return of the product.
- Retail and hospital pharmacies who are unable to confirm the lot number of COUMADIN 5 mg tablets dispensed to patients, should contact patients who have received COUMADIN 5 mg tablets between April 26, 2010 and receipt of this notification, and have them contact Stericycle for information related to the recall.

If you have any questions about this recall, please contact Stericycle at 1-866-918-8739.

Any adverse reactions should be reported to the FDA's MedWatch Program by fax at 1-800- FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at [www.fda.gov](http://www.fda.gov).