



June 25, 2010

**Immediate Attention Required  
Urgent Drug Recall:**

**COUMADIN® Tablets (Warfarin Sodium Tablets, USP) Crystalline, 1 mg,  
Hospital Unit Dose Blister Pack of 100  
NDC 0056-0169-75  
Isopropanol Below Specification**

<b>Strength</b>	<b>Lot Number</b>	<b>Item Number</b>	<b>Blister Card NDC</b>	<b>Expiration</b>
<b>1 mg</b>	<b>8F34006B</b>	<b>0169-75</b>	<b>0056-0169-01</b>	<b>30-JUN-2011</b>
<b>1 mg</b>	<b>8K44272A</b>	<b>0169-75</b>	<b>0056-0169-01</b>	<b>31-DEC-2011</b>
<b>1 mg</b>	<b>8K46168A</b>	<b>0169-75</b>	<b>0056-0169-01</b>	<b>31-JAN-2012</b>
<b>1 mg</b>	<b>9F44437A</b>	<b>0169-75</b>	<b>0056-0169-01</b>	<b>30-JUN-2012</b>
<b>1 mg</b>	<b>9K58012B</b>	<b>0169-75</b>	<b>0056-0169-01</b>	<b>30-NOV-2012</b>
Dates of distribution: September 2008 through April 2010				

Dear Customer:

Bristol-Myers Squibb Company is initiating a voluntary recall of the COUMADIN 1 mg Tablets Hospital Unit Dose Blister Pack lots listed above. The recall is based upon Bristol-Myers Squibb’s determination that some tablets, over time, may not meet specification for isopropanol, which is required to maintain the active ingredient in a crystalline state.

This recall is being conducted as a precautionary measure to the dispensing level with the knowledge of the US Food and Drug Administration (FDA), and is limited to the specific lots, dosage and packaging listed above.

Our medical assessment of this situation indicates that there does not appear to be a clinically important risk related to COUMADIN 1 mg Tablets in regard to isopropanol level. However, use of tablets with low isopropanol could in some cases potentially lead to patient-to-patient variation in bioavailability. All other product characteristics, including warfarin sodium assay, are within specification.

Our records indicate that you may have received product from the subject lots. **It is important that you carefully follow these recall instructions:**

1. Further distribution of the subject lots of COUMADIN 1 mg Tablets should cease immediately. You should return all remaining inventory of the subject lots to Bristol-Myers Squibb’s recall vendor, Stericycle, for product credit. Please complete and return the enclosed Business Reply Card even if you do not have any of the recalled stock in your possession.



## Bristol-Myers Squibb Company

2. If you are a wholesaler or warehousing customer, and have distributed these lots to other wholesalers, warehousing customers, hospitals, retailers or physician's offices, please contact these accounts immediately, advise them of the recall, and have them return their outstanding recalled stock to you for return to Bristol-Myers Squibb's recall vendor, Stericycle, for credit. Advise your customers that this recall is being conducted to the dispensing level.

**Please be certain to carefully review your lot numbers and return only the subject lots of COUMADIN Tablets (Warfarin Sodium Tablets, USP) Crystalline, 1 mg Blister Packs listed, including NDC 0056-0169-01 (blister card). Only product from these lots will be accepted for credit under the terms of this recall.**

If you have any questions about this recall, please refer to the contact numbers below for assistance:

Recall Logistics	Stericycle 1-877-546-0128
General Inquiries	Bristol-Myers Squibb Customer Relations 1-800-332-2056 (option 1, then option 4)
Medical Inquiries	Bristol-Myers Squibb Medical Information 1-800-321-1335 (option 5)
Reimbursement Process	Bristol-Myers Squibb Customer Service Operations 1-800-631-5244 (option 1, then option 5)

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance.