Coumadin 1 mg Tablet Blister Packs: Recall

FDA MedWatch

[Posted 07/14/2010]

AUDIENCE: Hematology, Cardiology, Risk Manager

ISSUE: Bristol-Myers Squibb determined that some of the tablets, over time, may not meet specification for isopropanol. Isopropanol is used to maintain the active ingredient, Coumadin, in the crystalline state, and could affect the therapeutic levels of the active ingredient. 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.

The following lot numbers are included in this recall: Physician Sample Blister Packs: Lot# 9A48931A, 9A48931B, 9A48931C, expiration January 2012; HUD Blister Pack: Lot# 8F34006B, 8K44272A, 8K46168A, 9F44437A and 9K58012B with expiry dates between June 2011 and November 2012.

BACKGROUND: The recall only involves Coumadin 1 mg tablet blister-packs distributed in the U.S. This recall does not involve Coumadin 1 mg supplied in bottles or any other strengths and dosage forms of the product. Patients who may have product from the subject lots should contact their physicians to ensure that their anticoagulation therapy is not interrupted.

RECOMMENDATION: See the company Press Release for additional contact information. 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:

- Online: www.fda.gov/MedWatch/report.htm [1]
- Phone: 1-800-332-1088
- Mail: return the postage-paid FDA form 3500, which may be downloaded from the MedWatch "Download Forms [2]" page, to address on the pre-addressed form
- Fax: 1-800-FDA-0178

[07/12/2010 - Press Release [3] - Bristol-Myers Squibb]

SOURCE [4]

Source URL (retrieved on *11/27/2014 - 5:11pm*):
http://www.ecnmag.com/news/2010/07/coumadin-1-mg-tablet-blister-packs-recall

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm218864.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm218955.htm