Pradaxa (dabigatran etexilate mesylate) Capsules: Special Storage and Handling Requirements

U.S. Food & Drug Administration

AUDIENCE: Pharmacy, Cardiology, Patients

ISSUE: FDA is alerting the public to important storage and handling requirements for Pradaxa (dabigatran etexilate mesylate) capsules. Due to the potential for product breakdown from moisture and loss of potency, Pradaxa capsules should only be dispensed and stored in the original bottle or blister package.

BACKGROUND: Pradaxa is an anticoagulant (blood thinner) medication known as a direct thrombin inhibitor. The Pradaxa label and Medication Guide contain information about these special storage and handling requirements, but FDA is concerned that these requirements are not commonly known and are not being followed by Pradaxa users and by pharmacies.

RECOMMENDATION: Pharmacists should only dispense Pradaxa in the original manufacturer bottle with the original dessicant cap. Do not repackage Pradaxa capsules in standard amber pharmacy vials. Patients should not store or place Pradaxa capsules in any other container, such as pill boxes or pill organizers. Open only one bottle of Pradaxa at a time. Once the bottle is opened, the product must be used within 60 days. Read the Medication Guide for Pradaxa for more information about these special storage and handling requirements.

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 [1]
- Download form [2] 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

[03/29/2011 - Drug Safety Communication [3] - FDA]

SOURCE [4]

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http://www.mdtmag.com/news/2011/03/pradaxa-dabigatran-etexilate-mesylate-capsules-special-storage-and-handling-requirements

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[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm248746.htm
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