



SASKATCHEWAN DRUG INFORMATION SERVICE

College of Pharmacy and Nutrition • University of Saskatchewan
110 Science Place • Saskatoon SK • S7N 5C9 • www.usask.ca/druginfo

RE: Pradox® (dabigatran) Storage and Dispensing Considerations

A number of questions and concerns have been expressed regarding the storage and dispensing of Pradox® (dabigatran). Dabigatran tablets are hygroscopic and should thus not be removed from their original packaging. In Canada, dabigatran is available to pharmacies in bottles or blisters.

- **Stock Bottles:**

If your pharmacy stocks bottles of Pradox®, the original bottle should be dispensed to the patient with instruction that the product must be used within 4 months following opening of the bottle (previous 1 month stability recently extended to 4 months based on new data).

- Individual capsules should **NOT** be placed into dosettes or blister packs because they will lose potency.

- **Blisters:**

The packaging of Pradox® capsules has been approved by Health Canada and guarantees that the product will be good for its pre-determined shelf life. Boehringer Ingelheim recommends that the Pradox® capsules are kept in the aluminium blister foil until just prior to taking them.

- If your pharmacy prepares individualized dosettes/blister packages, **ensure each Pradox® capsule remains in its original blister foil**. This will require manually cutting around each Pradox® capsule and placing each capsule into the pharmacy-prepared dosette/blister pack in its original blister foil.

When choosing drug therapy, patient dexterity (ie: ability to open individually wrapped Pradox®), home care policies, and other considerations related to the unique restrictions around the dispensing and storage of Pradox® should be recognized, as an alternative medication may be more appropriate for a particular patient, given such restrictions.

Considering the potentially life-threatening consequences of sub-therapeutic levels of dabigatran, related to a decrease in potency, we recommend dispensing Pradox® as outlined above until more information is available.

Prepared by Jaris P. Swidrovich, BSP, PharmD Student
November 15, 2012

References:

1. Boehringer Ingelheim (Manufacturer of Pradox®). November 8, 2012. <http://www.boehringer-ingelheim.ca/en/contact.html>
2. Electronic Compendium of Pharmaceuticals and Specialties (eCPS). Pradox® Product Monograph. Accessed November 7, 2012.
3. FDA Drug Safety Communication: Special storage and handling requirements must be followed for Pradaxa (dabigatran etexilate mesylate) capsules. Marc 29, 2011. Accessed November 7, 2012 from: <http://www.fda.gov/Drugs/DrugSafety/ucm248746.htm>

Telephone: 1-800-667-3425 (SK); 966-6340 (Saskatoon)
Fax: (306) 966-2286

