

Pradaxa® (dabigatran) in Blister Packs

In 2012, we posted a Hot Topic suggesting dabigatran not be removed from its original packaging due to stability concerns related to the hygroscopic nature of the drug. Since that time, the brand name has been changed, new stability data have been published, and the manufacturer has discontinued bottle packaging.

- **Blister Packs:**

- In 2012, we recommended Pradaxa® be excluded from community pharmacy blister packs or that capsules be cut from the manufacturer's aluminum blister packaging without disrupting the integrity of the packaging before including in the pharmacy blister packs.
- **Updated information:** a recent stability study has been conducted with findings that Pradaxa® **110 mg capsules remain stable for up to 120 days when packaged in community pharmacy blister packs** (Medpaks, Healthmark Industries Company Inc, Fraser, Michigan) and stored at room temperature.¹
 - The authors of the study note, "Also, because stability alone cannot guarantee bioavailability or efficacy, it is recommended that future clinical studies be conducted to evaluate the pharmacokinetics and pharmacodynamics of dabigatran etexilate after storage."
 - The pH of the capsule contents was measured throughout the study period with no changes; the authors noted the appearance and ease of suspension of capsule contents also did not change.
 - It is unlikely a clinical study will be conducted to assess Pradaxa® efficacy according to different storage conditions.
- Boehringer Ingelheim has blister cases available through regional sales representatives. Patients place a strip in the case which holds doses for 7 days, morning and evening. The patient can use the case to puncture the original packaging when it is time to take the capsule.²

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References:

1. Wang EHZ, Bolt JL, Decarie D, et al. Stability of dabigatran etexilate in manufacturer's blister pack, unit-dose packaging, and community pharmacy blister pack. CJHP 2015; 68(1): 16-21.
2. Personal communication, Boehringer Ingelheim (Canada) Medical Information. 14 Aug 2015