



Manufacturer initiates nationwide voluntary, patient level recall for one lot of Pradaxa®

On Nov. 7 Boehringer Ingelheim Pharmaceuticals, Inc. announced it is conducting a nationwide voluntary, patient-level recall of a single manufacturing lot of Pradaxa® (dabigatran etexilate mesylate), 75 mg.

This recall is being conducted due to a potential packaging defect on this lot that may compromise the bottle integrity. A damaged bottle could allow moisture to enter which may impair the quality of the product. As a consequence a patient may not receive a fully effective dose of Pradaxa, which would increase his or her risk of experiencing an ischemic stroke. This risk is small; however, not zero. Therefore, as a precautionary measure, Pradaxa is being recalled at the patient level.

- **Product and strengths:** Pradaxa® (dabigatran etexilate mesylate), 75 mg
- **Indication:** to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation
- **Manufacturer:** Boehringer Ingelheim Pharmaceuticals
- **Date of recall:** November 7, 2012
- **Type of recall:** voluntary, patient-level
- **Reason for recall:** potential packaging defect that may compromise the bottle integrity
- **NDC of recalled product:** 0597-0149-54
- **Affected lot number:** 201900, Exp January 2015
- **Legacy Medco patients impacted:** 103
- **Return/Replacement information:** The Express Scripts pharmacy is retrieving/replacing the affected product

Implications to Express Scripts and clients

Express Scripts is taking the following action in response to this recall:

- Notifying customer services representatives and pharmacists about the recall
- Posting web messaging on www.express-scripts.com
- Mailing letters to affected patients informing them about the recall and instructing them on what to do

Retail impact

- Retail patients will be managed by retail pharmacies according to their professional practices.

FOR MORE INFORMATION: Contact your Express Scripts Account Management Team.