

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2017-06

JUNE 8, 2017

**ITEM:
SPECIFIC
INCIDENT(S):**

Apixaban (Eliquis®) Recall Due to Incorrect Strength in Bottle

- Bristol-Myers Squibb Company is initiating a recall of one lot of apixaban (Eliquis®) 5 milligram (mg) tablets due to one field complaint of a single apixaban (Eliquis®) mg strength bottle containing lower-strength 2.5 mg tablets instead of the labeled 5 mg tablets.

**GENERAL
INFORMATION:**

- Apixaban (Eliquis®) is a factor Xa inhibitor used to reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation. It is also indicated for prevention and treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients who have undergone hip or knee replacement surgery.
- Affected lot includes:

NDC	Description	Lot Number	Expiration
0003-0894-21	ELIQUIS TAB 5 MG (1BTLX60) US	HN0063	SEP 2019

- Affected product started shipping February 13, 2017.
- This recall is an extension of the product sequestration actions in **Product Recall Office Log # 12024** (available at: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>).
- Providers should continue to report any adverse reactions with the use of apixaban (Eliquis®) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, cardiology, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 06/22/2017):
 - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
 - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
 - Identify the patient(s).
 - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
 - A sample letter can be found at:
<https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc>.
 - This template can be altered according to site-specific needs.
 - Provide patient(s) in possession of the recalled product with instructions on the following:
 - How to return the product being recalled to the pharmacy.
 - How to obtain a new supply of product.
 - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
 - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website:
<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>.

SOURCE: Manufacturer

REFERENCE(S): Bristol-Myers Squibb Company Recall Notification [Data on file, Date 06/06/17].

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.