

Bristol-Myers Squibb – Recall of Eliquis® (apixaban)

- On June 13, 2017, the <u>FDA announced</u> a consumer-level recall of one lot of <u>Bristol-Myers Squibb's</u> <u>Eliquis (apixaban)</u> 5 mg tablets due to a customer complaint that a bottle labeled as Eliquis 5 mg was found to contain Eliquis 2.5 mg tablets.
- The recalled lot was distributed in February 2017.

Product Description	NDC #	Lot # (Expiration date)
Eliquis (apixaban) 5 mg tablets, 60-count bottle	0003-0894-21	HN0063 (9/2019)

- Eliquis is indicated for the following: to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery; treatment of DVT and PE; and to reduce the risk of recurrent DVT and PE following initial therapy.
- Patients should not stop taking Eliquis without consulting with their healthcare provider.
 - Patients who are prescribed Eliquis 5 mg for atrial fibrillation and take an Eliquis 2.5 mg tablet instead, particularly for a prolonged period, would have an increased probability of stroke, a moving blood clot, or death.
 - For patients with DVT or PE, underdosing of Eliquis could lead to an increased risk of a growing or moving blood clot. Should that occur, it could be life-threatening or reversible depending on the severity and location of the blood clot. To date, there have not been any reports of injuries or illnesses related to this issue.
- There are distinct visible differences between the two Eliquis tablet strengths including colors, size and markings that distinguish the 2.5 mg and 5 mg tablets and decrease the likelihood of an incorrect dose.
 - The 2.5 mg presentation is a yellow, round, biconvex, film-coated tablet with "893" debossed on one side and "2½" on the other side.
 - The 5 mg presentation is a pink, oval, biconvex, film-coated tablet with "894" debossed on one side and "5" on the other side.
- Bristol-Myers Squibb has notified wholesalers and pharmacies to arrange for return and replacement
 of any recalled product. Consumers that have any recalled product should contact their healthcare
 provider and call the Bristol-Myers Squibb Customer Information Center at 1-800-332-2056 or visit
 BMS.com for more information.
- Consumers should contact their healthcare provider if they have experienced any problems that may
 be related to taking Eliquis.



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