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FDA approves first generics of blood thinner Eliquis

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The FDA granted approval of the generic apixaban applications to Micro Labs Limited and Mylan Pharmaceuticals Inc

The U.S. Food and Drug Administration has approved two applications for the first generics of Eliquis (apixaban) tablets to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. Apixaban is also indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery. Additionally, apixaban is indicated for the treatment of DVT and PE and for the reduction in the risk of recurrent DVT and PE following initial therapy.

"Today's approvals of the first generics of apixaban are an example of how the FDA's generic drug program improves access to lower-cost, safe and high-quality medicines," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "These approvals mark the first generic approvals of a direct oral anticoagulant. Direct oral anticoagulants (blood thinners) do not require repeated blood testing."

Addressing the challenges related to developing generics and promoting more generic competition is a key part of the FDA's Drug Competition Action Plan and the agency's efforts to help increase patient access to more affordable medicines.

For at-risk patients, such as those with, or at risk for, DVT, or nonvalvular atrial fibrillation, the risk of stroke related to blood clots forming in the body and traveling to the brain is a serious concern. Atrial fibrillation is a heart rhythm problem that can potentially cause such blood clots. According to the Centers for Disease Control and Prevention, it is estimated that between 2.7 and 6.1 million people in the U.S. have atrial fibrillation. Many of these individuals use anticoagulants or anti-clotting drugs to reduce that risk.

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