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FDA approves first generics of Eliquis

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To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation

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.

Apixaban will be dispensed with a Medication Guide for patients that provides instructions on its use and drug safety information. Health care professionals should counsel patients on signs and symptoms of possible bleeding.

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