Xarelto's approval expanded

November 5 2012

(HealthDay)—Approval of the anti-clotting drug Xarelto (rivaroxaban) has been expanded by the U.S. Food and Drug Administration to include treating deep vein thrombosis (DVT) or pulmonary embolism.

DVT occurs when a blood clot forms in a vein deep in the body. If a clot breaks away and travels to an artery in the lungs, it becomes a potentially deadly condition called a pulmonary embolism.

Xarelto was approved last year to treat clots stemming from knee or hip replacement and to lessen the risk of stroke in people with a form of abnormal heart rhythm called non-valvular atrial fibrillation.

The drug's newest approvals were given based on clinical studies involving 9,478 people, the FDA said in a news release. As with other anti-clotting drugs, bleeding is the most common side effect.

Xarelto is produced by Janssen Pharmaceuticals, based in Raritan, N.J.

More information: The FDA has more about this approval.