

FDA OKs new anti-clotting drug for heart rhythm disorder

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Savaysa works like warfarin but carries less bleeding risk.

(HealthDay)—A new anti-clotting drug to reduce the risk of dangerous blood clots and strokes in people with a type of heart rhythm disorder has been approved by the U.S. Food and Drug Administration.

Savaysa (edoxaban) is approved to treat people with [atrial fibrillation](#) that's not caused by a heart valve problem. Atrial fibrillation—the most common type of [heart rhythm disorder](#)—increases the risk of developing blood clots that can travel to the brain and cause a stroke.

Savaysa pills are also approved to treat [deep vein thrombosis](#) and [pulmonary embolism](#) in people already treated with an injected or infused anti-clotting drug for five to 10 days, according to the FDA.

Deep vein thrombosis is a blood clot that forms in a deep vein, usually in the lower leg or thigh. Pulmonary embolism is a potentially deadly condition that occurs when a deep vein blood clot breaks off and travels to an artery in the lungs, blocking blood flow.

"In patients with atrial fibrillation, anti-clotting drugs lower the risk of stroke by helping to prevent [blood clots](#) from forming in the heart," Dr. Norman Stockbridge, director of cardiovascular and renal products in the FDA's Center for Drug Evaluation and Research, said Thursday in an agency news release.

"It is important to have a variety of these types of drugs available as options for patients," he added.

The FDA approval of Savaysa is based on clinical trials that included more than 29,000 people.

In patients with atrial fibrillation, Savaysa reduced stroke risk as well as warfarin, a commonly used blood thinner, but with less major bleeding, the agency reported.

In the treatment of pulmonary embolism and deep vein thrombosis, slightly more patients taking warfarin had a recurrence compared to those taking Savaysa (3.5 percent versus 3.2 percent, respectively), according to the news release.

Savaysa carries a "boxed warning" alerting doctors that the drug is less effective in patients with poor kidney function. It recommends these patients be given another type of anti-clotting medication.

Savaysa is made by Daiichi Sankyo Co., Ltd. of Japan.

More information: The U.S. National Heart, Lung, and Blood

Institute has more about [atrial fibrillation](#).

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