Generic Name:
Edoxaban
Trade Name:
Savaysa
Company:
Daiichi Sankyo Co., Ltd.
Notes:

FDA has approved the anticlotting drug edoxaban to reduce the risk of stroke and dangerous blood clots in patients with atrial fibrillation that is not caused by a heart valve problem.

Edoxaban also has been approved to treat deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients who have already been treated with an anticlotting drug administered by injection or infusion for 5 to 10 days.

Safety and efficacy of edoxaban in treating patients with atrial fibrillation not caused by cardiac valve disease was studied in a clinical trial of 21,105 participants.The trial compared two dose levels of edoxaban with the anticlotting drug warfarin for their effects on rates of stroke and dangerous blood clots.

Trial results showed the higher dose of edoxaban to be similar to warfarin for the reduction in the risk of stroke. While warfarin is highly effective in reducing the risk of stroke in patients with atrial fibrillation, it increases the risk of bleeding. Edoxaban demonstrated significantly less major bleeding compared with warfarin.

Edoxaban for treatment of patients with DVT and PE was studied in 8,292 participants. The study compared the safety and efficacy of edoxaban to warfarin for treating patients with a DVT and/or PE to reduce the rate of recurrence of symptomatic venous thromboembolism (VTE) events (which includes DVT, PE, and VTE-related death). In the trial, 3.2% of participants taking edoxaban had a symptomatic recurrent VTE, compared with 3.5% of those taking warfarin.

The most common adverse effects observed in trial participants were bleeding and anemia. As with other FDA-approved anticlotting drugs, bleeding, including life-threatening bleeding, is the most serious risk with edoxaban. No treatment has been proven to reverse edoxaban's anticoagulant effect.

Edoxaban has a boxed warning that provides important dosing and safety information for health professionals about specific patient groups, including a warning that edoxaban is less effective in atrial fibrillation patients with a creatinine clearance greater than 95 mL per minute. This should be assessed before initiating therapy with edoxaban. Patients with creatinine clearance greater than 95 mL per minute have an increased risk of stroke compared with similar patients given warfarin. Edoxaban should not be used in nonvalvular atrial fibrillation patients with a higher creatinine clearance. Another anticoagulant should be used instead.

As with other anticoagulants, the boxed warning counsels that premature discontinuation of edoxaban increases the risk of stroke and notes that spinal or epidural hematomas may occur

in patients treated with edoxaban who are receiving anesthesia injected around the spine or undergoing spinal puncture.

Medication Monitor Categories:

New Drug Approvals
