Generic Name:
Rivaroxaban
Trade Name:
Xarelto
Company:
Bayer, Janssen
Notes:

Rivaroxaban is now approved to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF), according to a FDA news release. In September, the Cardiovascular and Renal Drugs Advisory Committee voted 9 to 2 in favor of recommending the drug for approval.

Approval was based on results of the pivotal, double-blind Phase III ROCKET-AF (Rivaroxaban Once-daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for the prevention of stroke and Embolism Trial in Atrial Fibrillation) trial, in which once-daily rivaroxaban was found to be noninferior to warfarin in terms of reducing the risk of stroke and systemic embolism in patients with nonvalvular AF. A major criticism of this trial was that warfarin-treated patients spent only 57.8 percent of the time in therapeutic range, which led some experts to question the wisdom of using rivaroxaban in patients who are well-controlled on warfarin therapy.

ROCKET-AF showed that major bleeding rates for rivaroxaban were comparable with those of warfarin. FDA has required a Risk Evaluation and Mitigation Strategy (REMS) for rivaroxaban to communicate the risks of increased risk of thrombotic events, including stroke, if the drug is discontinued without introducing an adequate alternative anticoagulant. The REMS consists of a Medication Guide and a communication plan.

The recommended dose for patients with nonvalvular AF is 20 mg once daily or 15 mg once daily for those with moderate to severe renal impairment. The dose should be taken with the evening meal. This dosing differs from the previous approved indication of venous thromboembolism prophylaxis in patients undergoing hip or knee surgery (10 mg once daily).

Medication Monitor Categories:
Supplemental Approvals
Use:

Reduce risk of stroke and systemic embolism in patients with nonvalvular AF