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

FDA has approved a new indication for rivaroxaban to reduce the risk of major cardiovascular (CV) events, such as CV death, myocardial infarction (MI) and stroke, in patients with chronic coronary or peripheral artery disease (CAD/PAD). It is now the first and only factor Xa inhibitor approved for patients with these conditions.

Approval was based on results from the COMPASS trial, which showed a significant 24% reduction in the risk of major CV events in patients with chronic CAD and/or PAD with the rivaroxaban 2.5-mg vascular dose twice daily plus aspirin 100 mg once daily, compared with aspirin alone.

This finding was driven by a 42% reduction in stroke, 22% reduction in CV death, and 14% reduction in heart attack. The risk of major bleeding was significantly higher in patients taking the rivaroxaban/aspirin regimen compared with aspirin alone, with no significant increase in fatal or intracranial bleeds.

Medication Monitor Categories:
Supplemental Approvals