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[Home](#) > FDA approves new indication in twice-daily dose for treatment of CAD and PAD

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:

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