

# VASCULAR PROTECTION

with Rivaroxaban 2.5mg b.i.d.  
& Aspirin o.d.<sup>3</sup>



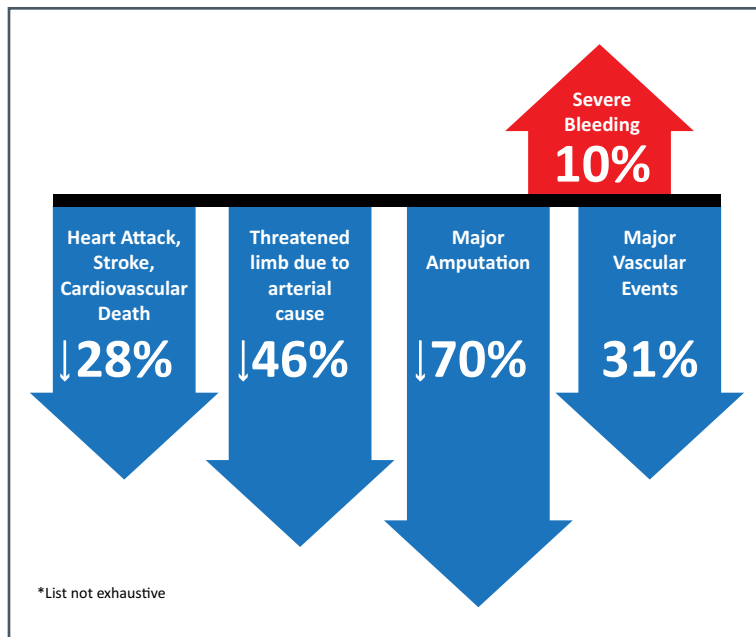
## What Physicians with Peripheral Arterial Disease (PAD) should know

### What are the benefits of this combination?

- **28% decrease** in stroke, heart attack or death from cardiovascular causes (MACE)
- **46% decrease** in acute loss of blood supply to leg including amputation (MALE)
- **70% decrease** in major amputations
- **31% decrease** in stroke, heart attack, CV death, major adverse limb events

### What are the drawbacks of this combination?

- **10% increase** in major bleeding
- Majority of bleeding is from the **gastrointestinal tract**
- **No significant increase** in severe bleeding, including bleeding into the brain or other critical organ causing death



### Additional Information

- The regimen of low-dose rivaroxaban and aspirin is based on a randomized trial called COMPASS-PAD<sup>1,2</sup>.
- The full trial name is "Rivaroxaban with or without aspirin in patients with stable peripheral or carotid artery disease: an international, randomised, double-blind, placebo-controlled trial".
- Low-dose rivaroxaban with aspirin was approved by the FDA, EMA and Health Canada in 2018.
- Severe bleeding is front loaded.<sup>4</sup>
- Net clinical benefit increases over time.<sup>4</sup>

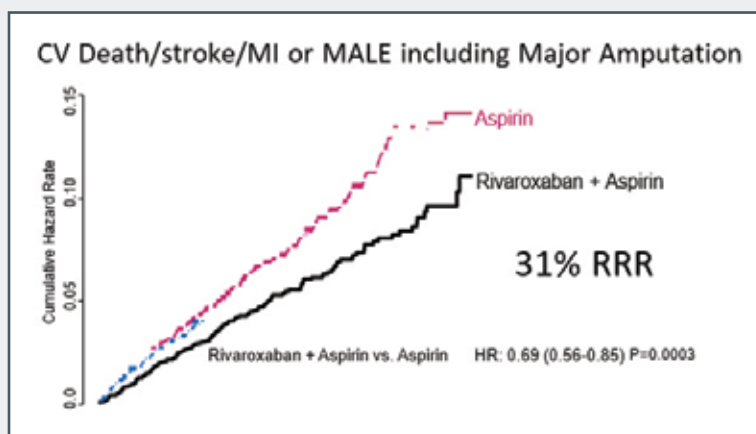


Figure: Cumulative incidence of cardiovascular complications, including amputation

#### References:

1. Anand, Sonia S., et al. "Rivaroxaban with or without aspirin in patients with stable peripheral or carotid artery disease: an international, randomised, double-blind, placebo-controlled trial." *The Lancet* 391.10117 (2018): 219-229.
2. Eikelboom, John W., et al. "Rivaroxaban with or without aspirin in stable cardiovascular disease." *New England Journal of Medicine* 377.14 (2017): 1319-1330.
3. Bayer Inc. (2018). PRODUCT MONOGRAPH: XARELTO. [online] Available at: <https://www.bayer.ca/omr/online/xarelto-pm-en.pdf> [Accessed 14 Oct. 2018].
4. Anand SS, et al. "Rivaroxaban Plus Aspirin Vs Aspirin in relation to Vascular Risk in the COMPASS trial." *J Am Coll Cardiol* 2019 July 2;73(25):3271-3280.

### Key Points

- Low-dose rivaroxaban and aspirin prevents MACE and MALE in PAD patients
- The patients who benefit the most from this therapy are: patients with vascular disease in 2 or more territories known as polyvascular disease, heart failure, renal insufficiency, or diabetes.<sup>4</sup>

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...continued

## What Patients with Peripheral Arterial Disease (PAD) should know

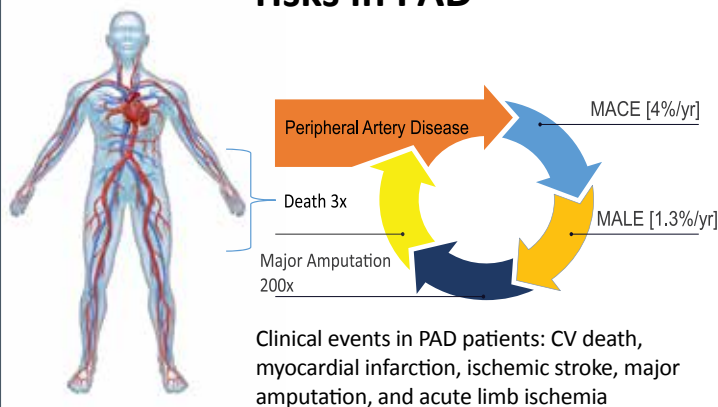
### How to take your medications

- Take rivaroxaban 2.5mg **twice per day**
- Take Aspirin 81mg **once per day**
- This medication regimen does not need monitoring
- **DO NOT SKIP DOSES**

### Medication Tips

- Make sure to **tell your doctors/dentists** you are taking this blood thinner before any surgeries or procedures, as you may need to stop taking it beforehand.
- Your dose of 2.5mg is the **lowest dose** of rivaroxaban available. Do not confuse this with the more common doses of 10mg, 15mg and 20mg. **This is sometimes different than the dose advertised on TV.**
- **Avoid non-steroidal anti-inflammatories (NSAIDs)** such as ibuprofen, naproxen and others while taking this combination.
- When prescribed a new medication, **ask your doctor or pharmacist** if it interacts with rivaroxaban.

### Addressing the major thrombotic risks in PAD



### Seek urgent medical attention if you develop

- Bowel movements that are bloody or black/tar-like
- Pink, red or very dark coloured urine
- New neurological concerns
- Excessive menstrual bleeding
- Coughing or vomiting of blood
- Any bleeding that won't stop
- Serious traumatic injury such as head trauma, broken bones or any major injury
- Significant paleness, weakness, shortness of breath or chest pain

### Do not take this regimen if

- You are at high risk for bleeding
- You take medication that interacts with rivaroxaban
- You need to take stronger blood thinners to treat blood clots or heart arrhythmias
- You have severe kidney or liver disease
- You are pregnant or breast feeding
- You have had an adverse reaction to rivaroxaban or aspirin
- You have had a brain bleed
- You drink significant amounts of alcohol

### Additional info:

- We continue to study the best use of blood thinners in patients with PAD, and may change your medications as new studies arise.
- Please contact your prescribing Dr. should you have any further questions regarding your therapy