

Peripheral artery disease – Information that may be of benefit prior to treatment with Xarelto® (rivaroxaban)

You have received this information because your doctor has prescribed you Xarelto for the treatment of peripheral artery disease. The information will help you understand the disease and why it is important for you to take Xarelto exactly as prescribed.

If you would like more information about peripheral artery disease, please contact your doctor or visit www.benartarsjukdom.se.

For complete user information, carefully read the package leaflet included with the medicine or visit www.fass.se.

Why do I need treatment?

Peripheral artery disease usually affects the blood vessels in the legs, the peripheral arteries.¹

The disease develops over time as fatty deposits (called plaque) build up inside your arteries and restrict blood flow. You then develop symptoms such as leg pain when your leg muscles need more oxygen than they get. It is usually most noticeable when you are out walking.¹ This condition is sometimes referred to as claudication.

"People don't understand that you have a disease. They think that you are just lazy and want to just stop and stare in the shop windows."

Minimise the risk

In some cases, a blood clot may form on top of the fatty deposit and block the artery completely. If this happens, surgery is needed to try to restore blood flow and reduce the risk of amputation.^{2,3} Luckily, there are medicines that you and your doctor can use to reduce the risk of this happening.

Why Xarelto®?

Your doctor has prescribed Xarelto in combination with acetylsalicylic acid as part of your peripheral artery disease treatment plan. This is intended to reduce the risk of a blood clot forming in your peripheral arteries.

What are Xarelto and acetylsalicylic acid?

Xarelto is a medicine that reduces your risk of blood clots forming in your peripheral arteries by making your blood a little thinner. Acetylsalicylic acid also works to thin the blood.

Why should I take both together?

Acetylsalicylic acid and Xarelto thin the blood in different ways, and it is more effective to take both together than to just take one of them.

The combination Xarelto and acetylsalicylic acid can reduce the risk of stroke, heart attack and amputation more effectively than acetylsalicylic acid alone.

How do Xarelto® and acetylsalicylic acid work?

Xarelto reduces fibrin network formation (the network that forms the blood clot), while acetylsalicylic acid reduces blood platelet activation (the cells that attach to the network). Together, they reduce the risk of a blood clot forming in your peripheral arteries.

How should I take Xarelto® and acetylsalicylic acid?

You need to take Xarelto twice a day and acetylsalicylic acid once a day. There are some tricks you can use to remember to take your medicine. Do you usually eat at the same times each day? Or is there something you use twice a day (for example, your toothbrush)?

Acetylsalicylic acid 75 mg once a day (in the morning OR in the evening). **Xarelto 2.5 mg** twice a day (in the morning AND in the evening).

Never take a double dose of Xarelto or acetylsalicylic acid to make up for a forgotten dose.

How long should I take Xarelto®?

Your doctor will decide how long you should continue treatment.

What more do I need to know about taking Xarelto®?

Patient card

You will be given a patient card to let healthcare professionals know that you are taking blood thinners. Show it to all doctors, dentists and nurses who treat you, and always carry it with you (for example, in your wallet) in case you are in an accident or become acutely ill.

What more can I do?

Remember that it is very important that you take your medicine according to your doctor's instructions. But, you can also help your coronary arteries in other ways:³

- ◆ Stop smoking
- ◆ Exercise regularly
- ◆ Lose weight, if you need to
- ◆ Eat a healthy diet

If you take more Xarelto® than you should

Contact your healthcare provider immediately if you have taken too many tablets. You are at a greater risk of bleeding if you take too much Xarelto.

Side effects

All medicines can cause side effects, although not everybody gets them. Contact your healthcare provider for advice if you start bleeding e.g. from your nose, mouth, urinary tract (e.g. blood in your urine) or stomach/bowel. If you have severe bleeding or bleeding that does not stop on its own, seek emergency care. If you suffer a severe blow to the stomach, chest or head, you should also seek emergency care to check for internal bleeding. Also seek emergency care if you develop unusual weakness, fatigue, paleness, dizziness, headache, unexplained swelling, increased shortness of breath, chest pain or angina, or symptoms that could be a sign of bleeding.

Use with other medicines

Do not take anti-inflammatory medicines such as Voltaren, Naproxen or additional acetylsalicylic acid without first asking your doctor. Painkillers containing paracetamol, such as Alvedon and Panodil, can be taken together with Xarelto without issue. **It is important to inform your doctor of any other medicines you may be using, including non-prescription medicines and herbal remedies. If you are using any antidepressant of the type SSRI, you should also inform your doctor of this.** Your doctor will decide how to handle your treatment.

Restrictions

Contact your doctor:

- ◆ if you are allergic, hypersensitive, to rivaroxaban or to any of the other ingredients of Xarelto
- ◆ if you bleed a lot or have an ongoing bleed
- ◆ if you have a liver disease or any other condition that results in an increased risk of bleeding
- ◆ if you are pregnant or breast-feeding
- ◆ if you are scheduled for surgery or a biopsy

If you need to undergo a dental procedure, like having a tooth pulled, contact your dentist and let them know that you are being treated with Xarelto. Also contact your doctor if you are planning to become pregnant.

NB: This booklet is not a substitute for advice and instructions from your doctor or other healthcare professional.

References:

1. Mayo Clinic. Peripheral artery disease (PAD). Symptoms and causes. Online at: <https://www.mayoclinic.org/diseases-conditions/peripheral-artery-disease/symptoms-causes/syc-20350557> [last read May 2020].
2. NHS Choices. Atherosclerosis (arteriosclerosis). Online at: <https://www.nhs.uk/conditions/atherosclerosis/> [last read May 2020].
3. Mayo Clinic. Peripheral artery disease (PAD). Diagnosis and treatment. Online at: <https://www.mayoclinic.org/diseases-conditions/peripheral-artery-disease/diagnosis-treatment/drc-20350563> [last read May 2020].

Xarelto (rivaroxaban), antitrombotiskt medel, **R** (B01 AF01). Tabletter 2,5 mg (F).

Indikation: Xarelto, i kombination med acetylsalicylsyra, är avsett för att förebygga aterotrombotiska händelser hos vuxna patienter med kranskärlssjukdom eller symptomatisk perifer kärlsjukdom med hög risk för ischemiska händelser. **Dosering:** Den rekommenderade dosen är Xarelto 2,5 mg två gånger dagligen, i kombination med en daglig dos om 75–100 mg acetylsalicylsyra. Behandlingslängden ska fastställas för varje enskild patient baserat på regelbundna utvärderingar med hänsyn tagen till risken för trombotiska händelser kontra blödningsrisk. **Kontraindikationer:** Överkänslighet mot den aktiva substansen eller mot något hjälpämne. Aktiv, kliniskt signifikant blödning. Organskada eller tillstånd, som anses utgöra en ökad risk för större blödning. Samtidig behandling med andra antikoagulantia. Samtidig behandling av akut koronart syndrom i kombination med trombocyttaggregationshämmande behandling hos patienter med tidigare stroke eller en transitorisk ischemisk attack (TIA). Samtidig behandling av kranskärlssjukdom/perifer kärlsjukdom med acetylsalicylsyra hos patienter med tidigare hemorragisk eller lakunär stroke, eller någon form av stroke inom en månad. Leversjukdom förknippade med koagulopati och kliniskt relevant blödningsrisk inkluderar

sive cirrhotiska patienter med Child Pugh B och C. Graviditet och amning. **Varningar och försiktighet:** Vid tillstånd med ökad blödningsrisk bör Xarelto användas med försiktighet. Administrering av Xarelto bör avbrytas om svår blödning uppstår. Xarelto ska användas med försiktighet hos patienter med kreatininclearance 15–29 ml/min. Användning av Xarelto hos patienter med kreatininclearance < 15 ml/min rekommenderas inte. Xarelto bör användas med försiktighet hos patienter med kranskärlssjukdom/perifer kärlsjukdom som är ≥ 75 år och samtidigt tar enbart acetylsalicylsyra eller acetylsalicylsyra och klopidogrel eller tiklopidin. Nyttan och risken med behandlingen ska regelbundet utvärderas för varje enskild individ. Datum för senaste översynen av produktresumén december 2022. Bayer AB. Box 606. 169 26 Solna. Tel. 08-580 223 00. För ytterligare information samt priser se www.fass.se. Före förskrivning vänligen läs produktresumén på fass.se MA-M_Riv-SE-0142-3. December 2022.

Översättningen är utförd av *LanguageWire*, ett professionellt ISO9001:2015-certifierat översättningsföretag med kompetens att översätta från svenska till engelska. Vi intygar härmed att denna översättning, enligt vår professionella kunskap, motsvarar dokumentet *Patientbroschyr (PAD)* på svenska.



Bayer AB
Box 606, 169 26 Solna
Tel: 08-580 223 00