The Xarelto® Legacy

Experience across 8 indications

Xarelto® is indicated for:

Prevention of stroke and systemic embolism in patients with atrial fibrillation, in whom anticoagulation is appropriate.

Prevention of stroke, myocardial infarction and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with coronary artery disease (CAD) with or without peripheral artery disease (PAD).

Prevention of atherothrombotic events in patients with symptomatic PAD at demonstrated high risk of major adverse limb events (MALE) or major adverse cardiovascular and cerebrovascular events (MACCE).

2.5 mg, in combination with
75 mg–100 mg acetylsalicylic acid (ASA)

Treatment of VTE (deep vein thrombosis [DVT], pulmonary embolism [PE]) and prevention of recurrent DVT and PE.

Prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip replacement (THR) or total knee replacement (TKR) surgery.

10 mg, 15 mg, 20 mg

Treatment of venous thromboembolic events (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

20 mg

Treatment of venous thromboembolic events (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

15 mg

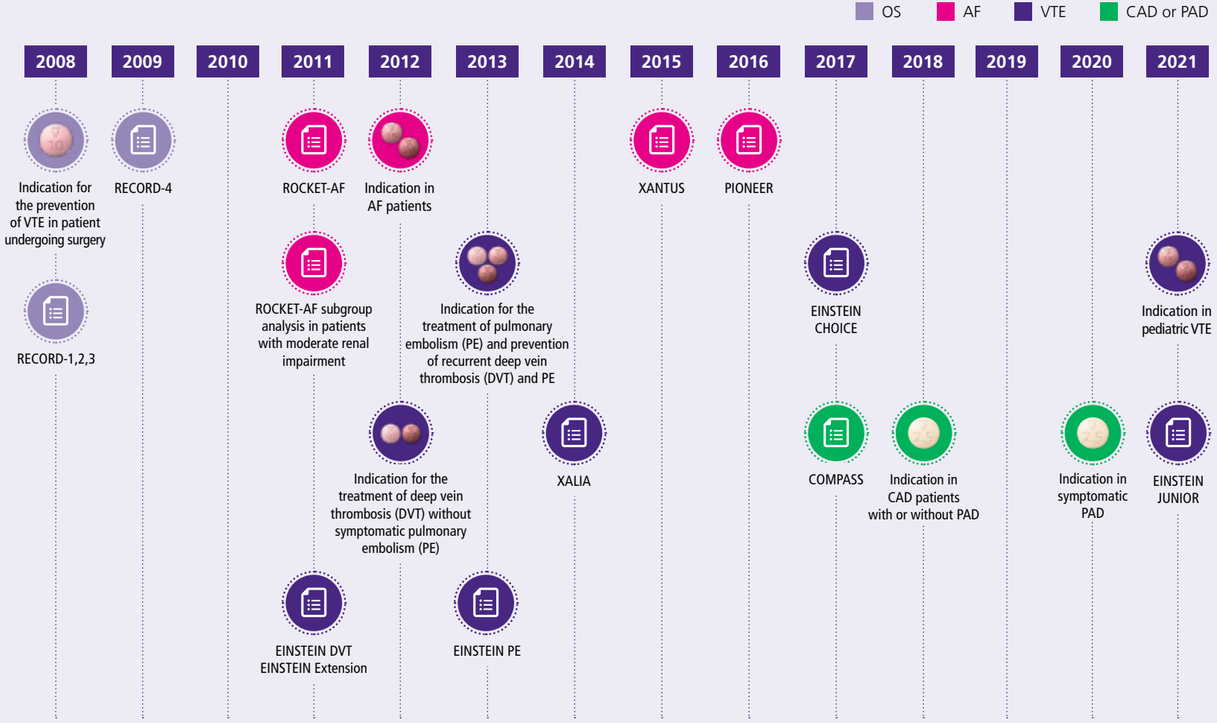
Treatment of venous thromboembolic events (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment.

1 mg/mL oral granules for suspension

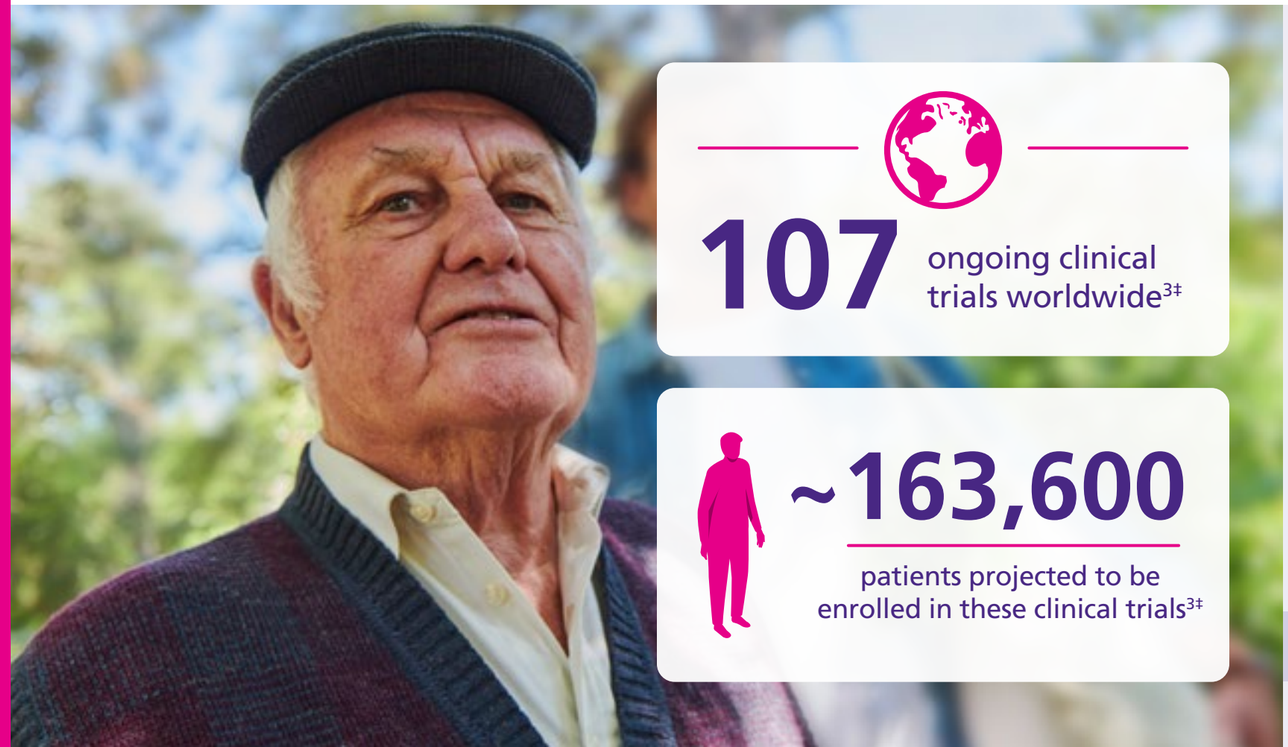
Xarelto® rivaroxaban tablet

Global experience

Xarelto® – Trust in our 12 years of experience



Xarelto® – Commitment to ongoing clinical research[3‡]



107 ongoing clinical trials worldwide[3‡]

~163,600 patients projected to be enrolled in these clinical trials[3‡]

The initiation of ongoing clinical trials intended to evaluate the efficacy and/or safety of Xarelto®‡

- Target Enrollment: N=450
  Rivaroxaban in the Treatment of Venous Thromboembolism (VTE) in Cancer Patients – a Randomized Phase III Study (CONKO)
- Target Enrollment: N=2,000
  Treatment of Cardiovascular Disease with Low Dose Rivaroxaban in Advanced Chronic Kidney Disease (TRACK)
- Target Enrollment: N=4,000
  Xarelto + Acetylsalicylic Acid: Treatment Patterns and Outcomes Across the Disease Continuum in Patients with CAD and/or PAD (XATOC)

Xarelto® – A legacy of commitment to clinical research and patient care

Xarelto®: Trust in our experience

12 years
of experience

Launched in
130
countries[2]

78 million
patients treated in clinical practice worldwide

107
ongoing clinical trials worldwide[3‡]

~163,600
patients projected to be enrolled in these clinical trials[3‡]

† Xarelto® is indicated for the treatment of venous thromboembolic events (deep vein thrombosis [DVT], pulmonary embolism [PE]) and prevention of recurrent DVT and PE; the prevention of stroke and systemic embolism in patients with atrial fibrillation, in whom anticoagulation is appropriate; the prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip replacement (THR) or total knee replacement (TKR) surgery; and the prevention of stroke, myocardial infarction (MI) and cardiovascular (CV) death, and for the prevention of acute limb ischemia and mortality in patients with coronary artery disease (CAD) with or without peripheral artery disease (PAD).[1]

‡ Clinical trials may be unaffiliated with Bayer. Data has been sourced from the U.S. National Library of Medicine (http://www.clinicaltrials.gov) database on February 3, 2021.

Consult the Product Monograph at www.bayer.ca/omr/online/xarelto-pm-en.pdf for important information about:

- Contraindications in patients with clinically significant active bleeding, including gastrointestinal bleeding; lesions or conditions at increased risk of clinically significant bleeding; concomitant systemic treatment with strong inhibitors of both CYP 3A4 and P-glycoprotein (P-gp); concomitant treatment with any other anticoagulant including: unfractioned heparin (UFH), low-molecular-weight heparins (LWMH), heparin derivatives, and oral anticoagulants; hepatic disease (including Child-Pugh Class B and C) associated with coagulopathy and having clinically relevant bleeding risk; pregnancy; nursing women; and hypersensitivity to Xarelto® or to any ingredient in the formulation.
- The most serious warnings and precautions regarding increased risk of thrombotic events with premature discontinuation of any oral anticoagulant; bleeding; peri-operative spinal/epidural anesthesia, lumbar puncture; use in patients with severe renal impairment; use in pediatric patients with renal impairment monitoring and laboratory tests: INR is not a valid measure to assess the anticoagulant activity of Xarelto®.
- Other relevant warnings and precautions regarding excipients; fall in hemoglobin or blood pressure; concomitant use of drugs affecting hemostasis; chronic concomitant treatments with NSAIDs if receiving Xarelto® 2.5 mg with ASA; atrial fibrillation and having a condition that warrants single or dual antiplatelet therapy (DAPT); use of Xarelto® 2.5 mg and ASA in patients with CAD with or without PAD, in combination with or as a replacement for DAPT; or in patients with symptomatic PAD at demonstrated high risk of MALE or MACCE; use of antiplatelet agents; use of thrombolytics during acute myocardial infarction (AMI) or acute stroke; patients with prosthetic heart valves, or other valve procedures or those with hemodynamically significant rheumatic heart disease; patients diagnosed with antiphospholipid syndrome and with a history of thrombosis; patients with atrial fibrillation who undergo PCI with stent placement, CAD/PAD patients with history of previous hemorrhagic or lacunar stroke; CAD/PAD patients in the first month after ischemic non-lacunar stroke; interactions with strong inhibitors of both CYP 3A4 and P-gp; dronedarone; patients with mild and moderate renal impairment concomitantly treated with combined P-gp and moderate CYP 3A4 inhibitors; interaction with strong CYP 3A4 inducers; patients with hepatic impairment; patients who undergo surgery or invasive procedures to the lower limbs patients with lactose sensitivity; use of Xarelto® 2.5 mg BID + ASA in patients with chronic CAD with or without PAD or in patients with symptomatic PAD at demonstrated high risk of MALE or MACCE ≥75 years of age.
- Conditions of clinical use, adverse reactions, drug interactions and dosing/administration instructions.

References:
1. Xarelto® (rivaroxaban) Product Monograph. Bayer Inc. January 6, 2021.
2. Data on file. IQVIA MIDAS, Database Quarterly Sales Q3 2019. Bayer Inc.
3. ClinicalTrials.gov. Last accessed March 12, 2021.

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