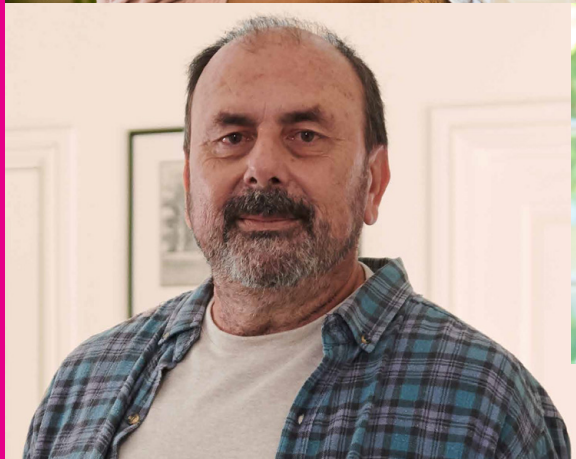
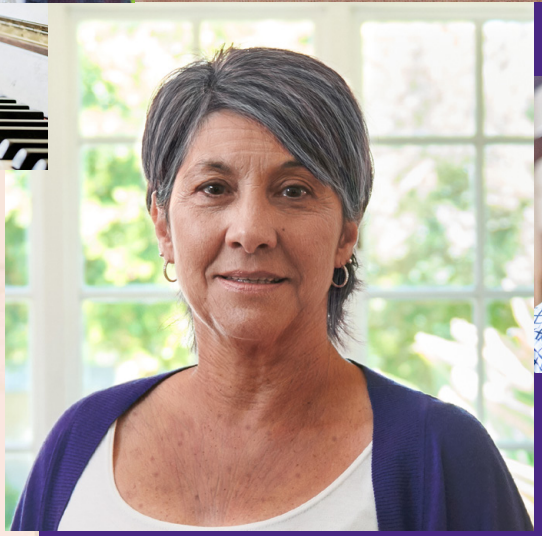
Xarelto®
Dosing Guide†

† Please consult the Product Monograph for complete dosing and administration instructions.

Xarelto® rivaroxaban tablet



PrXarelto® (rivaroxaban) film-coated tablet (10 mg, 15 mg, 20 mg) is indicated for the:

- prevention of stroke and systemic embolism in patients with atrial fibrillation (AF), in whom anticoagulation is appropriate.
- treatment of venous thromboembolic events (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.

Xarelto® film-coated tablet (2.5 mg), in combination with 75 mg-100 mg ASA, is indicated for 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).
- 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).

Xarelto® granules for oral suspension (1 mg/mL) is indicated for the:

- 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.

Xarelto® film-coated tablet (15 mg) is indicated for the:

- 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.

Xarelto® film-coated tablet (20 mg) is indicated for the:

- 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.

For the treatment of VTE, Xarelto® is **not** recommended as an alternative to unfractionated heparin in patients with acute pulmonary embolus who are hemodynamically unstable, or who may receive thrombolysis or pulmonary embolectomy, since the safety and efficacy of Xarelto® have not been established in these clinical situations.

ASA: acetylsalicylic acid

Xarelto® Dosing Guide

Prevention of stroke and systemic embolism in patients with AF in whom anticoagulation is appropriate

Normal renal function or mild renal impairment

CrCl >80 mL/min CrCl 50-<80 mL/min	**ONCE** daily  Xarelto® 20 mg OD

Moderate and severe renal impairment†

CrCl 30-<50 mL/min CrCl 15-<30 mL/min Use with caution	**ONCE** daily  Xarelto® 15 mg OD

Xarelto® 15 and 20 mg should be taken with food.

The **1st** and **only** NOAC with dosing instructions and precautions for nonvalvular AF patients undergoing PCI with stent placement in its Product Monograph[2§]

Xarelto® Dosing Guide

Recommended dose for nonvalvular AF patients who undergo percutaneous coronary intervention (PCI) with stent placement[1]

Reduce Xarelto® dose Add a $P2Y_{12}$ inhibitor Maximum of 12 months	Increase Xarelto® dose Remove antiplatelet Revert back to standard dose after completion of the antiplatelet therapy

After PCI

Xarelto® 15 mg‡ OD
+ $P2Y_{12}$ inhibitor

Xarelto® 20 mg OD

In patients with moderate renal impairment (CrCl 30-49 mL/min), the Xarelto® reduced dose should be 10 mg OD during concomitant treatment with $P2Y_{12}$ inhibitor and 15 mg OD after completion of antiplatelet therapy.

† Xarelto® should not be used in patients with CrCl <15 mL/min; use with caution in patients with CrCl 15-<30 mL/min and in patients with CrCl 30-<50 mL/min, especially in those concomitantly receiving other medicinal products that increase rivaroxaban plasma concentration. Physicians should consider the benefit/risk of anticoagulant therapy before administering Xarelto® to patients with moderate renal impairment having a creatinine clearance close to the severe renal impairment category (CrCl <30 mL/min), or in those with a potential to have deterioration of renal function to severe impairment during therapy. Patients who develop acute renal failure while on Xarelto® should discontinue such treatment.

‡ In PCI patients with moderate renal impairment (CrCl 30-49 mL/min), the Xarelto® reduced dose should be 10 mg OD during concomitant treatment with $P2Y_{12}$ inhibitor and 15 mg OD after completion of antiplatelet therapy.

§ Comparative clinical significance is unknown.

AF: atrial fibrillation; CrCl: creatinine clearance; OD: once daily; PCI: percutaneous coronary intervention

Xarelto® Dosing Guide

CAD

Prevention of stroke, MI and CV death, and prevention of acute limb ischemia and mortality in CAD patients with or without PAD

Vascular protection regimen

TWICE daily

Xarelto®
2.5 mg BID

ASA
75-100 mg OD

Xarelto® 2.5 mg twice daily is not indicated in combination with dual antiplatelet therapy.

Xarelto® 2.5 mg may be taken with or without food.

BID: twice daily; CAD: coronary artery disease; CV: cardiovascular; MI: myocardial infarction; PAD: peripheral artery disease

Xarelto® Dosing Guide

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)

Vascular protection regimen

TWICE daily

Xarelto®
2.5 mg BID

ASA
75-100 mg OD

Xarelto® 2.5 mg twice daily is not indicated in combination with dual antiplatelet therapy.

Xarelto® 2.5 mg may be taken with or without food.

BID: twice daily; PAD: peripheral artery disease

Xarelto® Dosing Guide

VTE (adult)

Treatment of VTE (DVT, PE) and prevention of recurrent DVT and PE

Initial treatment - day 1 to 21

TWICE daily

Xarelto® 15 mg BID

Continued treatment - from day 22†

ONCE daily

Xarelto® 20 mg OD

Prevention of recurrent DVT and PE - Following completion of at least 6 months of treatment

ONCE daily

Xarelto® 10 mg OD

Dose based upon individual risk/benefit assessment

ONCE daily

Xarelto® 20 mg OD

† The duration of therapy should be individualized after careful assessment of the treatment benefit against the risk of bleeding. Short duration of therapy (at least 3 months) should be based on transient risk factors (e.g., recent surgery, trauma, immobilization). Longer duration of therapy should be considered in patients with DVT or PE provoked by permanent risk factors, unprovoked DVT or PE, or a history of recurrent DVT or PE.

BID: twice daily; DVT: deep vein thrombosis; VTE: venous thromboembolic events; PE: pulmonary embolism

Xarelto® Dosing Guide

Xarelto® 10 mg tablets may be taken with or without food.
Xarelto® 15 mg and 20 mg should be taken with food.

For the treatment of VTE, Xarelto® is **not** recommended as an alternative to unfractionated heparin in patients with acute pulmonary embolus who are hemodynamically unstable, or who may receive thrombolysis or pulmonary embolectomy, since the safety and efficacy of Xarelto® have not been established in these clinical situations.

Xarelto® Dosing Guide

VTE (pediatric)

Treatment of VTE and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged <18 years after at least 5 days of initial parenteral anticoagulation treatment

Dose is determined based on body weight

Dosage form		Administration
1. Tablet (15 mg or 20 mg) 	**15 mg tablet** For children and adolescents with: • body weight of 30 kg to 50 kg **20 mg tablet** For children and adolescents with: • body weight of >50 kg	• Once-daily dosing • Swallow with liquid • Taken with a feeding or with food • Each Xarelto® dose should be immediately followed by the intake of one typical serving of liquid‡ • **Do not** split the Xarelto® 15 mg or 20 mg tablet in an attempt to provide a fraction of a tablet dose§

Therapy with Xarelto® should be continued for at least 3 months in all children, except those aged <2 years with catheter-related thrombosis. Treatment can be extended up to 12 months when clinically necessary. The benefit-risk of continued therapy after 3 months should be assessed on an individual basis considering the risk for recurrent thrombosis versus the potential bleeding risk.

Xarelto® is the first and only NOAC indicated in pediatric patients[2†]

Xarelto® Dosing Guide

Dose and frequency of administration is determined based on body weight

Dosage form		Administration
2. Granules for oral suspension* 	For term neonates, infants¶, children and adolescents with: • body weight of at least 2.6 kg	• Administer the oral suspension by mouth with the oral dosing syringe* – Before administration the granules must be suspended with water into homogenous suspension – Shake the bottle after reconstitution and before each dose • Taken with a feeding or with food • Each Xarelto® dose should be immediately followed by the intake of one typical serving of liquid† • See the Product Monograph for dose calculation and dosing frequency

Xarelto® treatment requires at least 10 days of oral feeding. Three oral dosing syringes are supplied. The correct one should be used for the corresponding dosage.

In patients age <2 years with catheter-related thrombosis, therapy with Xarelto® should be continued for at least 1 month; treatment can be extended up to 3 months when clinically necessary. For all other children, therapy with Xarelto® should be continued for at least 3 months and can be extended up to 12 months when clinically necessary. The benefit-risk of continued therapy after 3 months should be assessed on an individual basis considering the risk for recurrent thrombosis versus the potential bleeding risk.

VTE: venous thromboembolic events; NOAC: novel oral anticoagulant

* Complete details on preparation and administration of the oral suspension can be found in the Instructions for Use that is provided with the medicinal product.

† Comparative clinical significance has not been established.

‡ This typical serving may include liquid volume used for feeding. In case the patient immediately spits up the dose or vomits within 30 minutes after receiving the dose, a new dose should be given. However, if the patient vomits more than 30 minutes after the dose, the dose should not be re-administered and the next dose should be taken as scheduled.

§ For children who are unable to swallow whole 15 mg or 20 mg tablets, Xarelto® granules for oral suspension should be used. If the granules for oral suspension are not immediately available, please refer to administration of crushed tablets.

¶ Dosing of Xarelto® cannot be reliably determined and was not studied in children less than 6 months of age who: at birth had less than 37 weeks of gestation, have a body weight of less than 2.6 kg, or had less than 10 days of oral feeding. Xarelto® is therefore not recommended in these children.

Notes

Notes

Please consult the Xarelto® Product Monograph at www.bayer.com/sites/default/files/2020-11/xarelto-pm-en.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling 1-800-265-7382.

Reference: 1. Xarelto® (rivaroxaban) Product Monograph. Bayer Inc. January 6, 2021.

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REVIEWED BY PAAB

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