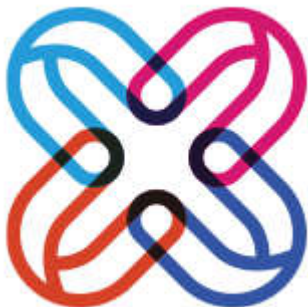


www.drugs.com /sfx/xarelto-side-effects.html

Xarelto Side Effects



Generic name: *rivaroxaban*

Medically reviewed by [Philip Thornton, DipPharm](#). Last updated on Jan 18, 2023.

Note: This document contains side effect information about rivaroxaban. Some dosage forms listed on this page may not apply to the brand name Xarelto.

Applies to [rivaroxaban](#): **oral powder for suspension, oral tablet.**

Warning

Oral route (Tablet)

Premature discontinuation of any oral anticoagulant, including rivaroxaban, increases the risk of thrombotic events. To reduce this risk, consider coverage with another anticoagulant if rivaroxaban is discontinued for a reason other than pathological bleeding or completion of a course of therapy. Epidural or spinal hematomas, which may result in long-term or permanent paralysis, have occurred in patients treated with rivaroxaban who are receiving neuraxial [anesthesia](#) or undergoing spinal puncture. Optimal timing between the administration of rivaroxaban and neuraxial procedures is not known. Factors that can increase the risk of developing hematomas include: use of indwelling epidural catheters; concomitant use of drugs affecting hemostasis, such as [NSAIDs](#), platelet inhibitors, or other [anticoagulants](#); or a history of traumatic or repeated epidural or spinal punctures, spinal deformity, or spinal surgery. Monitor patients frequently for neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider risks/benefits before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

Serious side effects of Xarelto

Along with its needed effects, rivaroxaban (the active ingredient contained in [Xarelto](#)) may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking rivaroxaban:

More common

- [Back pain](#)
- bleeding gums
- bloody stools
- bowel or bladder dysfunction
- burning, crawling, itching, [numbness](#), prickling, "pins and needles", or tingling feelings
- [coughing up blood](#)
- difficulty with breathing or swallowing
- [dizziness](#)
- [headache](#)
- increased menstrual flow or [vaginal bleeding](#)
- leg weakness
- [nosebleeds](#)
- numbness
- paralysis
- prolonged bleeding from cuts
- red or black, tarry stools
- red or dark brown urine
- [vomiting](#) of blood or material that looks like coffee grounds

Less common

- Fainting
- [pain](#) in the arms or legs
- wound secretion

Rare

- Burning feeling while urinating
- difficult or painful urination

Incidence not known

- Blistering, peeling, or loosening of the skin
- blurred vision
- chest tightness

- chills
- clay-colored stools
- cough
- dark urine
- [diarrhea](#)
- fast or [irregular heartbeat](#)
- [fever](#) with or without chills
- general feeling of tiredness or weakness
- [hives](#), itching, [skin rash](#)
- hoarseness
- joint or muscle pain
- loss of appetite
- lower back or side pain
- [nausea](#)
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- red skin lesions, often with a purple center
- red, irritated eyes
- severe headache
- [sore throat](#)
- sores, ulcers, or white spots in the mouth or on the lips
- stomach pain or swelling
- unpleasant breath odor
- unusual bleeding or bruising
- unusual tiredness or weakness
- vomiting
- yellow eyes or skin

Other side effects of Xarelto

Some side effects of rivaroxaban may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Less common

- Blisters
- [muscle spasm](#)

For Healthcare Professionals

Applies to rivaroxaban: **oral granule for reconstitution, oral kit, oral tablet.**

General

The most common adverse reactions were bleedings/bleeding complications/bleeding events.^[Ref]

Cardiovascular

Common (1% to 10%): [Hypotension](#), hematoma, hypertension, [tachycardia](#), procedural hypotension, [deep vein thrombosis](#)

Uncommon (0.1% to 1%): Traumatic hematoma

Rare (0.01% to 0.1%): Vascular pseudoaneurysm

Frequency not reported: Hypoperfusion, cardiac ischemia symptoms (e.g., chest pain, [angina pectoris](#)), decreased blood pressure^[Ref]

Dermatologic

Common (1% to 10%): [Pruritus](#), rash, ecchymosis, cutaneous hemorrhage, subcutaneous hemorrhage, blister, unspecific blistering, subcutaneous hematoma

Uncommon (0.1% to 1%): Generalized pruritus, [angioedema](#), [allergic dermatitis](#), [urticaria](#), ecchymosis, skin hemorrhage, drug eruption, pruritic rash, erythematous rash, generalized rash

Very rare (less than 0.01%): [Toxic epidermal necrolysis](#)

Frequency not reported: Generalized urticaria, maculopapular rash, viral rash

Postmarketing reports: [Stevens-Johnson syndrome](#), drug reaction with [eosinophilia](#) and systemic symptoms (DRESS), [angioedema](#)^[Ref]

Gastrointestinal

Very common (10% or more): Nausea (up to 11.1%)

Common (1% to 10%): Gingival bleeding, gastrointestinal (GI) tract hemorrhage, rectal hemorrhage, GI pain, [abdominal pain](#), [dyspepsia](#), [constipation](#), diarrhea, vomiting, upper abdominal pain, major GI bleeding, GI bleeding events (included upper GI bleeding, lower GI bleeding, [rectal bleeding](#)), GI hemorrhage

Uncommon (0.1% to 1%): Dry mouth, increased lipase, increased amylase, anal hemorrhage, hematemesis, hematochezia, [hemorrhoidal](#) hemorrhage, lower GI hemorrhage, melena, lip hemorrhage, mouth hemorrhage, tongue hemorrhage, abdominal discomfort, lower abdominal pain, occult blood positive, upper GI hemorrhage, gastric ulcer hemorrhage, hemorrhagic [gastritis](#), gastric hemorrhage

Rare (0.01% to 0.1%): Nonfatal retroperitoneal bleeding

Frequency not reported: [Gastroenteritis](#) (including viral gastroenteritis), stomach discomfort, epigastric discomfort^[Ref]

Genitourinary

Common (1% to 10%): Urogenital tract hemorrhage, [hematuria](#), [menorrhagia](#), [urinary tract infection](#), [urinary retention](#), vaginal hemorrhage

Uncommon (0.1% to 1%): Metrorrhagia, blood urine present

Rare (0.01% to 0.1%): Menometrorrhagia

Frequency not reported: Abnormal vaginal/increased menstrual bleeding^[Ref]

Hematologic

Major bleeding was defined as clinically overt bleeding associated with a decrease in Hb of at least 2 g/dL, a transfusion of at least 2 units of packed RBCs/whole blood, bleeding at a critical site, or with a fatal outcome.

Clinically relevant nonmajor bleeding was bleeding that was clinically overt, did not meet the criteria for major bleeding, but was associated with medical intervention, unscheduled contact with physician, temporary cessation of therapy, discomfort for patient, or impairment of daily life activities.

Modified ISTH major bleeding was defined as fatal bleeding; symptomatic bleeding in a critical area or organ (e.g., intraarticular, IM with compartment syndrome, intraspinal, intracranial, intraocular, respiratory, pericardial, liver, pancreas, retroperitoneal, adrenal gland, kidney); bleeding into the surgical site requiring reoperation; or bleeding leading to hospitalization.

Nonfatal noncritical organ bleeding was major bleeding that was not fatal or in a critical organ, but resulted in a decrease in Hb of at least 2 g/dL and/or transfusion of at least 2 units of packed RBCs/whole blood.

Fatal bleeding was adjudicated death with the primary cause of death from bleeding^[Ref]

Very common (10% or more): Any bleeding (up to 28.3%)

Common (1% to 10%): [Anemia](#) (including respective laboratory parameters), postprocedural hemorrhage (including postoperative anemia, wound hemorrhage), hemorrhage, [thrombocytosis](#), major bleeding, clinically relevant nonmajor bleeding, modified International Society on Thrombosis and Hemostasis (ISTH) major bleeding, bleeding leading to hospitalization (nonfatal, noncritical organ, not requiring reoperation), Thrombolysis in Myocardial Infarction Bleeding Criteria (TIMI) major bleeding (coronary artery bypass graft [CABG]/non-CABG), clinically overt signs of hemorrhage associated with a drop in hemoglobin (Hb) of at least 5 g/dL or drop in hematocrit of at least 15%

Uncommon (0.1% to 1%): Increased platelet count, operative hemorrhage, traumatic hemorrhage,

decreased Hb, decreased hematocrit, bleeding varicose vein, nonfatal symptomatic bleeding in critical organ, decrease in Hb of at least 2 g/dL, nonfatal noncritical organ bleeding, transfusion of at least 2 units of packed RBCs/whole blood, nonfatal critical organ bleeding, bleeding that required reoperation, extra-surgical site bleeding requiring transfusion of more than 2 units of whole blood/packed cells, critical site bleeding, bleeding into a critical organ, fatal bleeding event

Rare (0.01% to 0.1%): Bleeding into the surgical site requiring reoperation (nonfatal noncritical organ), fatal non-intracranial bleeding

Frequency not reported: Trivial bleeding

Postmarketing reports: [Agranulocytosis](#), [thrombocytopenia](#)^[Ref]

Hepatic

Common (1% to 10%): Increased transaminases (including increased ALT, increased AST), increased GGT, increased ALT

Uncommon (0.1% to 1%): Hepatic impairment, increased bilirubin, increased AST, abnormal liver function test, increased hepatic enzyme, increased conjugated bilirubin (with or without concomitant increase of ALT), [hyperbilirubinemia](#)

Postmarketing reports: [Jaundice](#), cholestasis, hepatitis (including hepatocellular injury)^[Ref]

Hypersensitivity

Uncommon (0.1% to 1%): Allergic reaction

Postmarketing reports: Hypersensitivity, [anaphylactic reaction](#), [anaphylactic shock](#), allergic [edema](#)^[Ref]

Metabolic

Uncommon (0.1% to 1%): Hyperglycemia^[Ref]

Musculoskeletal

Common (1% to 10%): Pain in extremity, contusion, back pain, muscle spasm, arthralgia, increased muscle cramping

Uncommon (0.1% to 1%): Hemarthrosis

Rare (0.01% to 0.1%): Muscle hemorrhage

Frequency not reported: Compartment syndrome (secondary to bleeding)^[Ref]

Nervous system

Intracranial bleeding events included intraparenchymal, intraventricular, subdural, subarachnoid, and/or epidural hematoma. [Hemorrhagic stroke](#) referred to nontraumatic intraparenchymal and/or intraventricular hematoma in patients on therapy plus 2 days.^[Ref]

Common (1% to 10%): Dizziness, headache, [syncope](#), increased muscle tone

Uncommon (0.1% to 1%): [Cerebral hemorrhage](#), loss of consciousness, [intracranial hemorrhage/bleeding](#), nonfatal intracranial hemorrhage/bleeding, hemorrhagic stroke (fatal and nonfatal), other intracranial hemorrhage/bleeding (fatal and nonfatal), fatal intracranial hemorrhage/bleeding

Rare (0.01% to 0.1%): Subdural hematoma, cerebellar hemorrhage, hemorrhagic transformation stroke

Postmarketing reports: Hemiparesis^[Ref]

Ocular

Common (1% to 10%): Eye hemorrhage, conjunctival hemorrhage

Uncommon (0.1% to 1%): Vitreous hemorrhage, periorbital hematoma

Rare (0.01% to 0.1%): Nonfatal intraocular bleeding^[Ref]

Other

Common (1% to 10%): Pyrexia/fever, peripheral edema, decreased general strength and energy, [fatigue](#), asthenia, wound secretion, unspecific pain, wound healing complications, feeling unwell, wound hemorrhage

Uncommon (0.1% to 1%): Increased blood alkaline phosphatase, malaise, increased lactate dehydrogenase, incision site hemorrhage

Rare (0.01% to 0.1%): Localized edema, feeling abnormal

Frequency not reported: Mucosal bleedings (i.e., epistaxis, gingival, gastrointestinal, genitourinary [including abnormal vaginal/increased menstrual bleeding])^[Ref]

Psychiatric

Common (1% to 10%): [Insomnia](#), [anxiety](#), [depression](#), [sleep disorders](#)^[Ref]

Renal

Common (1% to 10%): Renal impairment (including increased blood creatinine, increased blood [urea](#))

Uncommon (0.1% to 1%): Decreased renal CrCl, increased blood creatinine, increased blood urea

Frequency not reported: [Renal failure](#)/acute renal failure (secondary to bleeding sufficient to cause

hypoperfusion)^[Ref]

Respiratory

Common (1% to 10%): Epistaxis/nosebleed, hemoptysis, [dyspnea](#)

Frequency not reported: Pulmonary hemorrhage, pulmonary hemorrhage with [bronchiectasis](#), epistaxis leading to transfusion, cough^[Ref]

Frequently asked questions

References

1. "Product Information. Xarelto (rivaroxaban)." Janssen Pharmaceuticals (2022):
2. "Product Information. Xarelto (rivaroxaban)." Bayer Australia Ltd (2020):
3. "Product Information. Xarelto (rivaroxaban)." Bayer Plc (2022):

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Some side effects may not be reported. You may report them to the [FDA](#).

[Medical Disclaimer](#)