

RIVAROXABAN (XARELTO®)

GUIDELINES FOR ANTICOAGULATION UPDATED JULY 2017

This guideline provides a summary of the inpatient management of **adult** (over the age of 18) patients receiving RIVAROXABAN. This guideline should be used in conjunction with Therapeutic Goods Administration (TGA) approved [Product Information](#), [Clinical Excellence Commission \(CEC\) Non-Vitamin K Antagonist Oral Anticoagulant \(NOAC\) Guidelines](#) and specialist advice.

Commencing treatment:

Conduct the following prior to commencing treatment:

- Full blood count (FBC)
- Prothrombin time (PT)
- Activated Partial Thromboplastin Time (aPTT)
- Liver Function Test (LFT)
- Renal function - estimated creatinine clearance (CrCl) should be calculated using the [Cockcroft-Gault equation](#) (do not use eGFR reported in pathology results). [Ideal body weight](#) should be used for calculating estimated creatinine clearance in patients who are overweight or obese. For all other patients use actual body weight.

Further investigate if results are found to be abnormal.

Review the following:

Contraindications to therapy, drug and antithrombotic interactions, and administration considerations.

Contraindications to therapy⁽¹⁾:

- Known hypersensitivity
- Creatinine clearance <30mL/min for therapeutic dose or CrCl <15 mL/min for prophylactic dose [prevention of VTE after elective total hip replacement (THR) or total knee replacement (TKR)]
- Clinically significant active bleeding
- Significant inherited or acquired bleeding disorder
- Hepatic disease with coagulopathy (Child-Pugh B and C)
- Organ lesions at risk of bleeding including intracranial haemorrhage in previous six months
- Indwelling spinal or epidural catheter and during the first six hours after removal
- Mechanical heart valve
- Pregnancy or breastfeeding mother

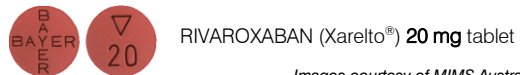
Caution: In patients with any history of gastrointestinal bleeding use RIVAROXABAN with caution and seek advice.



RIVAROXABAN (Xarelto®) 10 mg tablet



RIVAROXABAN (Xarelto®) 15 mg tablet



RIVAROXABAN (Xarelto®) 20 mg tablet

Images courtesy of MIMS Australia. Images not to scale.

Drug Interactions*⁽¹⁾

Class or medicine (Not an exhaustive list)	Advice
Anticonvulsants <i>phenytoin, carbamazepine, phenobarbitone</i>	Caution
Azole antifungals <i>e.g. itraconazole voriconazole, posaconazole</i>	Contraindicated
HIV protease inhibitors <i>e.g. ritonavir</i>	Contraindicated
Macrolides <i>e.g. clarithromycin, erythromycin</i>	Caution
Rifampicin	Caution
St John's Wort	Caution
Verapamil	Uncertain

* SSRI and SNRI are not listed in the Product Information; however concurrent use may theoretically increase risk of bleeding

Antithrombotic interactions⁽¹⁾

Action	Example (Not an exhaustive list)	Advice
Antiplatelet	NSAIDs Aspirin Clopidogrel Prasugrel Dipyridamole Ticagrelor	Caution
	Dual-antiplatelets	Relative contraindication
Anticoagulant	Warfarin Enoxaparin Heparin	Contraindicated (unless transitioning between anticoagulants)

Administration considerations/ instructions:

- 10 mg tablet may be taken with or without food
- The 15 mg and 20 mg tablet should be taken with food
- Can be crushed (See [Don't Rush to Crush Handbook](#))
- Tablets can be used in dose administration aids, e.g. Webster-pak®.

RIVAROXABAN (Xarelto®) dosing⁽¹⁾

Indication	Risk factors*	Dose	Duration
Prevention of stroke and systemic embolism in non-valvular AF in patients with at least one of the following risk factors: <ul style="list-style-type: none"> prior stroke, TIA or non-central nervous system systemic embolism; age ≥ 75 years, hypertension, diabetes mellitus or heart failure and/ or left ventricular ejection fraction ≤ 35%. 	Patient with: CrCl 30 – 49 mL/min	RIVAROXABAN 15 mg once daily	Indefinite duration
	Patient with: CrCl ≥50 mL/min	RIVAROXABAN 20 mg once daily	Indefinite duration
Prevention of VTE following**: <ul style="list-style-type: none"> Total Hip Replacement (THR) or Total Knee Replacement (TKR) 	Patient with: CrCl 15 - 29 mL/min	RIVAROXABAN 10 mg once daily (use with caution)	THR = 35 days TKR = 14 days
	Patient with: CrCl ≥30 mL/min	RIVAROXABAN 10 mg once daily	THR = 35 days TKR = 14 days
Treatment of VTE and prevention of recurrent VTE	Patient with: CrCl ≥30 mL/min	RIVAROXABAN 15 mg twice daily	3 weeks
		then RIVAROXABAN 20 mg once daily	According to patient requirement

*RIVAROXABAN is contraindicated in patients with CrCl <30mL/min for treatment dose **or** CrCl <15 mL/min for prophylactic dose (prevention of VTE after elective THR or TKR)

**Initial dose should be taken 6-10 hours after surgery provided that haemostasis has been established

Perioperative management

- A recent **CrCl** result should be available.
- For urgent or high bleeding risk elective surgery conduct: estimated **CrCl**, PT and FBC. Consider anti-Xa level (where available).
- Refer to [CEC NOAC Guidelines](#) for advice on spinal, epidural anaesthesia, or lumbar puncture.

Timing of ceasing RIVAROXABAN prior to surgery⁽¹⁾

RIVAROXABAN (Xarelto®)	Minimal bleeding risk procedures*	Low bleeding risk procedures*	High bleeding risk procedures*
Normal/ mildly impaired renal function (CrCl >50 mL/min)	Withholding RIVAROXABAN may not be required	Last dose 24 hours before surgery	Last dose 48 – 72 hours before surgery
Moderately impaired renal function (CrCl 30 - 50 mL/min)	Withholding RIVAROXABAN may not be required	Last dose 48 hours before surgery	Last dose 72 hours before surgery
CrCl <30 mL/min	SEEK SPECIALIST ADVICE		

*Refer to [CEC NOAC Guidelines](#) for information on minimal, low and high bleeding risk procedures.

Recommencing NOAC post-operatively⁽²⁾

Low bleeding risk surgery

- Start or resume 24 hours after surgery.

High bleeding risk surgery

- Do not start or resume therapeutic dosing until 48 – 72 hours after surgery
- Consider alternative VTE prophylaxis in the interim.

THR and TKR prophylaxis with NOAC may be recommenced 24 hours after surgery.

References: 1. Bayer Australia LTD. Product Information Xarelto® (Rivaroxaban). Therapeutic Goods Administration Website (updated 14 July 2017). 2. Tran H, Joseph J, Young L, McRae S, Curnow J, Nandurker H, et al. New oral anticoagulants: a practical guide on prescription, laboratory testing and peri-procedural/bleeding management Internal Medicine Journal 2014; 44: 525-36

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Managing Bleeding

Mild bleeding

- Establish dose and last time taken
- Initiate standard resuscitation procedures
- Consider: FBC, group and hold, **CrCl**, PT, anti-Xa level (where available)
- Establish if taking any other medicines with antiplatelet action
- Seek advice from a senior medical officer whether to delay dose or discontinue
- Refer to [CEC NOAC Guidelines](#).

Clinically significant or life-threatening bleeding

- As above
- Consult haematologist
- Refer to [CEC NOAC Guidelines](#). (NB: No reversal agent available in Australia)