



MONOGRAPH

RIVAROXABAN

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [DISCLAIMER](#)

! HIGH RISK MEDICINE !

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring
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DRUG CLASS

Factor Xa inhibitor anticoagulant (direct oral anticoagulant [DOAC]).^{1,2}

- Rivaroxaban directly inactivates clotting factor Xa by selectively blocking its active site and decreasing thrombin generation. It has no direct effect on platelet aggregation but indirectly inhibits platelet aggregation induced by thrombin.¹
- Rivaroxaban is a [High Risk Medicine](#).

INDICATIONS AND RESTRICTIONS

- Continuation anticoagulation therapy for patients > 12 kg with venous thromboembolism (VTE) who have completed a minimum of 5 days' initial heparin or enoxaparin therapy.
- Rivaroxaban may only be prescribed under the direction of a Haematologist.

CONTRAINDICATIONS

- Hypersensitivity to rivaroxaban or any component of the formulation.²
- Active major bleeding.^{1,2}
- Haemophilia or other bleeding disorders.²

- Severe renal impairment – in infants < 12 months of age, avoid when serum creatinine > 97.5th percentile; in children ≥ 12 months of age, avoid when eGFR < 50 mL/min/1.73m².^{1,2}
- Moderate to severe hepatic impairment (coagulopathy, ALT > 5 times the upper limit of normal (ULN) or total bilirubin > 2 x ULN with conjugated fraction > 20%).³
- Use with dual P-glycoprotein / CYP3A4 inhibitors or CYP3A4 inducers.^{1,2}
- Pregnancy and breastfeeding.^{1,2}

PRECAUTIONS

- Disease states with increased risk of bleeding (e.g. inflammatory bowel disease, haemorrhagic or ischaemic cerebral infarction).²
- Thrombocytopenia (platelet count < 50 x 10⁹L).²
- Surgical patients:
 - Withhold rivaroxaban for 24 hours prior to surgery with minor bleeding risk or 48 hours prior to surgery with major bleeding risk.²
 - Resumption of rivaroxaban will depend on the post operative bleeding risk and will require confirmation with the treating Surgeon and Haematologist on a case-by-case basis. As a rule, it should not be resumed within 24 hours of surgery.

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Rivaroxaban 2.5 mg, 10 mg, 15 mg and 20 mg tablets

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Not recommended due to lack of a commercially available suspension and insufficient pharmacokinetic / pharmacodynamic data to support the use of partial doses prepared from the 2.5 mg tablet in paediatric patients.

Dosing in Overweight and Obese Children: Limited information is available regarding safety and efficacy of rivaroxaban in obese paediatric patients. Recommend alternative anticoagulation in patients with BMI > 40 kg/m² or weighing > 120 kg.⁴

Dosing regimen for paediatric VTE based on EINSTEIN-Jr phase 3 study³:

Weight	Dose
12 kg – 29.9 kg	5 mg Twice daily PO
30 kg – 49.9 kg	15 mg daily PO
> 50 kg	20 mg daily PO

Give with or after food. Tablets may be crushed and mixed with water or apple puree.^{5,6}

Renal impairment:

- [eGFR calculator](#)
- Avoid in infants < 12 months old when serum creatinine > 97.5th percentile.^{1,2}
- Avoid in children ≥ 12 months old if eGFR < 50 mL/min/1.73m².^{1,2}

Hepatic impairment:

- Avoid in moderate to severe hepatic impairment (coagulopathy, ALT > 5 x ULN or total bilirubin > 2 x ULN with conjugated fraction >20%).³

MONITORING

- Prior to initiation of rivaroxaban therapy: baseline full blood picture (FBP), coagulation profile, renal function and hepatic function testing.²
- Routine laboratory monitoring of rivaroxaban is not required
- If there are concerns regarding severe bleeding, overdose or the need for urgent reversal, a rivaroxaban level can be performed by the laboratory at PathWest QEII. This should be discussed with the Haematologist on-call.

Reversal of rivaroxaban:

- There is currently no specific reversal agent approved for paediatric use in Australia.
- In the event of a clinically urgent need for managing the effects of rivaroxaban, prothrombin complex concentrate (Beriplex® AU), may be given off-label in consultation with the Haematologist on-call.
 - **Note:** Beriplex® AU does not directly reverse the anticoagulant effect but is aimed at managing major bleeding and major bleeding risk in an emergency.
 - Beriplex® AU stock is kept in the Transfusion Laboratory at PathWest QEII.
 - Refer to [Direct Oral Anticoagulants \(DOACs\) – Management of Bleeding Patients](#).

ADVERSE EFFECTS¹⁻³

Common: Bruising, heavy menstrual bleeding, epistaxis, vomiting

Infrequent: Skin rash, pruritus, abdominal pain, gastrointestinal bleeding, increased serum transaminases, fatigue

Rare: Major haemorrhage, hepatotoxicity, Stevens-Johnson syndrome, toxic epidermal necrolysis, hypersensitivity reactions

STORAGE

Store below 30°C.⁷

Store tablets in original pack until required.⁷

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. [Clinical Pharmacology](#)), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **rivaroxaban**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

[BERIPLEX®AU & BERIPLEX® P/N- \(Factors II, VII, IX & X\) HUMAN PROTHROMBIN COMPLEX](#)

References

1. Rivaroxaban. *Clinical Pharmacology powered by ClinicalKey* [Internet]. Philadelphia (PA): Elsevier; c2026- [cited 2026 Sep 4]. Available from: <https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/monograph/3548?n=Rivaroxaban>
2. Rivaroxaban: Pediatric drug information. *UpToDate Lexidrug* [Internet]. Wolters Kluwer; [cited 2026 Sep 4]. Available from: [Rivaroxaban: Pediatric drug information - UpToDate \(health.wa.gov.au\)](#)
3. Male C et al. Rivaroxaban compared with standard anticoagulants for the treatment of acute venous thromboembolism in children: a randomised, controlled, phase 3 trial. *Lancet Haematol* 2020 Jan;7(1):e18-e27.
4. Canadian Pediatric Thrombosis and Hemostasis Network (CPTHN). *Rivaroxaban use in pediatric patients*. Final guidance document. Hamilton (ON): CPTHN; 2021 Sep [cited 2026 Sep 4]. Available from: <https://cpthn.ca/wp-content/uploads/2023/01/CPTHN-Rivaroxaban-Guidance-Document-Final-Sep-2021-002.pdf>
5. Australian Medicines Handbook Children's Dosing Companion [Internet]. Adelaide: Australian Medicines Handbook Pty Ltd; 2026 Jul. Rivaroxaban [cited 2026 Sep 4].

Available from: <https://childrens-amh-net-au.pklibresources.health.wa.gov.au/monographs/rivaroxaban>

6. Advanced Pharmacy Australia. *Don't Rush to Crush* [Internet]. Melbourne: Advanced Pharmacy Australia; 2025 [cited 2026 Sep 4]. Rivaroxaban. Available from: <https://dontrushtocrush-tg-org-au.pklibresources.health.wa.gov.au/monograph/rivaroxaban#Enteral%20feeding%20tubes>
7. AusDI [Internet] Telstra Health. [Accessed June 4 2025] Available from: [Ixxarola - AusDI](#)

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File Path:	W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\Medication Monographs_Word\PCH.MED.Rivaroxaban.docx		
Document Owner:	Chief Pharmacist		
Reviewer / Team:	Haematologist, Senior Pharmacist, Haematology CNS		
Date First Issued:	September 2026	Last Reviewed:	September 2026
Amendment Dates:		Next Review Date:	September 2029
Approved by:	PCHN Medication Safety Committee	Date:	Sep 2026
Endorsed by:	CAHS Drug & Therapeutics Committee	Date:	Oct 2026
Standards Applicable:	NSQHS Standards:   NSMHS: N/A Child Safe Standards: N/A		

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