# Beriplex® Anticoagulation Reversal Quick Reference Guide

This interim guide is to support the use of BERIPLEX® in **Anticoagulation Reversal** where local guidelines have not yet been updated (awaiting national guideline by THANZ#). **Lower doses** are used in other settings including **cardiac surgery, trauma** & in patients with other thrombotic risk factors, seek specific expert guidance.

- BERIPLEX® is a 4-factor prothrombin complex concentrate (PCC) with FII, FVII, FIX, FX (also contains heparin, proteins C & S). It replaces Prothrombinex®-VF (3-factor PCC). **Ensure the prescription is written for the correct product** available locally.
- Indications, contraindications, precautions are consistent with Prothrombinex®-VF.
- For Haematology advice consult on-call haematologist / critical bleeding consultant.

## Rapid reversal of warfarin effect with Beriplex® 4-factor PCC & IV Vitamin K

| Clinical setting | Interim# Guidance for Beriplex® in international units (IU) | | |
|---|---|---|---|
| **INR ≥ 1.5** with life-threatening (critical organ) bleeding, including intracranial bleeding | **Cease warfarin therapy and administer:**<br>• **vitamin K** 5 –10 mg IV (0.3 mg/kg IV, max 10mg for children)<br>• ***and* Beriplex** 50 IU/kg IV based on weight capped at 100 kg. Consider dose <50 IU/kg if INR 1.5 – 1.9 or as per expert advice.<br>• **FFP is not required for reversal of the warfarin effect** as Beriplex contains all 4 vitamin K-dependent clotting factors.<br>• FFP may be required for associated major haemorrhage as directed by the local Massive Transfusion Protocol (MTP). | | |
| **INR ≥ 2.0** with clinically significant bleeding (not life-threatening) | **Cease warfarin therapy and administer:**<br>• **vitamin K** 5 –10 mg IV (0.3 mg/kg IV, max 10mg for children)<br>• ***and* Beriplex** 25 – 50 IU/kg IV according to individual patient factors & INR, **see below**, based on weight capped at 100 kg. | | |
| **Pre-treatment INR** | **2.0 - 3.9** | **4.0 - 6.0** | **> 6.0** |
| Approx. dose IU/kg body weight | 25 IU/kg | 35 IU/kg | 50 IU/kg |

Vial size is 500 IU. Individualised dosing considerations include: type/degree of bleeding; nature, availability, timeliness of haemostatic interventions; thrombotic risks (indication for warfarin, others). **Where PCC may be indicated in a non-bleeding patient** (eg. urgent surgery; INR > 10 with high risk of bleeding), same dose of Beriplex can be considered as the Prothrombinex dose indicated for **these settings** in existing local warfarin reversal protocols (until updated) - consult haematologist.

**Dosing of Beriplex® for DOAC reversal:** when indicated, dose is 25 – 50 IU/kg (max. 5000 IU). Refer to local guidelines / MTP protocol, consult haematologist.

## Administration of Beriplex®

- **Reconstitution:** 500 IU with 20 mL Water for Injection using Mix2Vial in box. Swirl **do not** shake. Do not mix with any other drugs, diluents, solutions or blood products.
- **No blood** should be in the infusion line: flush with 0.9% Normal Saline pre & post-dose. Do not pull back to check for blood (fibrin clot may develop).
- **Infusion rates:** not exceeding 3 IU/kg body weight/minute (0.12 mL/kg/min), up to a maximum of 210 IU/min (approx. 8 mL/min).

**Weight-based adult infusion rates:** calculate if weight 40 kg or less (see above):

| | |
|---|---|
| **> 40 – 65 kg** | each 1000 IU (40 mL) over at least **8 mins** (max. 5 mL/min or 300 mL/hr) |
| **> 65 kg** | each 1000 IU (40 mL) over at least **5 mins** (max. 8 mL/min or 480 mL/hr) |

- **Batch number must be documented**: to ensure traceability for adverse events.

Developed by SA Critical Bleeding Advisory Group as an interim guide. Does not replace clinical judgment & expert guidance for individual patients. Refer to local protocols once updated. #Thrombosis & Haemostasis Society of Australia & New Zealand is updating their Warfarin reversal & DOAC Guidelines. Once completed, see: https://www.thanz.org.au/resources/thanz-guidelines

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# **Beriplex® 4 Factor PCC - Warfarin Reversal** Nomogram for use ONLY when 50 IU/kg dose is indicated

**For reversal of Warfarin effect, INR ≥ 1.5 WITH life-threatening (critical organ) bleeding, including intracranial bleeding:**

- **Beriplex 50 IU/kg** IV based on weight capped at 100 kg (consider a lower dose of <50 IU/kg if INR 1.5 – 1.9 or as per expert advice based on individual patient factors) & **IV vitamin K**.

Refer to page above (Beriplex QRG) for dosing in non life-threatening reversal of warfarin effect & dosing in NOAC reversal.

**Beriplex 4 Factor PCC: 50 IU/kg dose.** Use closest weight & round dose. Calculate dose & rate if weight <40 kg.

| **Weight** | 50 IU/kg Dose (IU) | **50 IU/kg Dose rounded (IU)** | No. 500 IU vials | No. syringes 40 mL per syringe | Volume to be infused mL | **Maximum rate mL/minute** | **Maximum rate mL/hour** | Minimum time for infusion of dose (minutes) |
|---|---|---|---|---|---|---|---|---|
| **40 kg** | 2000 | **2000** | 4 | 2 | 80 | **5** | **300** | 16 |
| **45 kg** | 2250 | **2500** | 5 | 2.5 | 100 | **5** | **300** | 20 |
| **50 kg** | 2500 | **2500** | 5 | 2.5 | 100 | **6** | **360** | 16 |
| **55 kg** | 2750 | **3000** | 6 | 3 | 120 | **6** | **360** | 20 |
| **60 kg** | 3000 | **3000** | 6 | 3 | 120 | **7** | **420** | 17 |
| **65 kg** | 3250 | **3500** | 7 | 3.5 | 140 | **7** | **420** | 20 |
| **70 kg** | 3500 | **3500** | 7 | 3.5 | 140 | **8** | **480** | 17 |
| **75 kg** | 3750 | **4000** | 8 | 4 | 160 | **8** | **480** | 20 |
| **80 kg** | 4000 | **4000** | 8 | 4 | 160 | **8** | **480** | 20 |
| **85 kg** | 4250 | **4500** | 9 | 4.5 | 180 | **8** | **480** | 22 |
| **90 kg** | 4500 | **4500** | 9 | 4.5 | 180 | **8** | **480** | 22 |
| **95 kg** | 4750 | **5000** | 10 | 5 | 200 | **8** | **480** | 25 |
| **≥ 100 kg** | 5000 | **5000** | 10 | 5 | 200 | **8** | **480** | 25 |

- Reconstitute with WFI using Mix2Vial in box. Swirl **do not** shake. Do not mix with any other drugs, diluents, solutions or blood products.
- No blood should be in the infusion line: flush with 0.9% Normal Saline pre & post-dose. Do not pull back to check for blood (fibrin clot may develop).
- Give according to the minimum infusion time / maximum rate above, as a slow push or via a syringe driver. Batch No. must be documented.

Table uses weight-based rates from PI: rate not exceeding 3 IU/kg body weight/minute (0.12 mL/kg/min), to max. of 210 IU/min (approx. 8 mL/min).

Vial size is 500 IU reconstituted with 20 mL WFI (25 IU/mL). PCC = Prothrombin Complex Concentrate. IU = International Units. WFI = Water for Injection.

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