

# Beriplex<sup>®</sup> Anticoagulation Reversal Quick Reference Guide

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

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

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

Clinical setting	Interim <sup>#</sup> Guidance for Beriplex <sup>®</sup> in international units (IU)		
<b>INR ≥ 1.5</b> with life-threatening (critical organ) bleeding, including intracranial bleeding	<b>Cease warfarin therapy and administer:</b> <ul style="list-style-type: none"> <li>• <b>vitamin K</b> 5 –10 mg IV (0.3 mg/kg IV, max 10mg for children)</li> <li>• <b>and Beriplex</b> 50 IU/kg IV based on weight capped at 100 kg. Consider dose &lt;50 IU/kg if INR 1.5 – 1.9 or as per expert advice.</li> <li>• <b>FFP is not required for reversal of the warfarin effect</b> as Beriplex contains all 4 vitamin K-dependent clotting factors.</li> <li>• FFP may be required for associated major haemorrhage as directed by the local Massive Transfusion Protocol (MTP).</li> </ul>		
<b>INR ≥ 2.0</b> with clinically significant bleeding (not life-threatening)	<b>Cease warfarin therapy and administer:</b> <ul style="list-style-type: none"> <li>• <b>vitamin K</b> 5 –10 mg IV (0.3 mg/kg IV, max 10mg for children)</li> <li>• <b>and Beriplex</b> 25 – 50 IU/kg IV according to individual patient factors &amp; INR, <b>see below</b>, based on weight capped at 100 kg.</li> </ul>		
<b>Pre-treatment INR</b>	<b>2.0 - 3.9</b>	<b>4.0 - 6.0</b>	<b>&gt; 6.0</b>
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<sup>®</sup> 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<sup>®</sup>

- > **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):

<b>&gt; 40 – 65 kg</b>	each 1000 IU (40 mL) over at least <b>8 mins</b> (max. 5 mL/min or 300 mL/hr)
<b>&gt; 65 kg</b>	each 1000 IU (40 mL) over at least <b>5 mins</b> (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 [Beriplex Quick Reference Guide](#) 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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