

Beriplex®

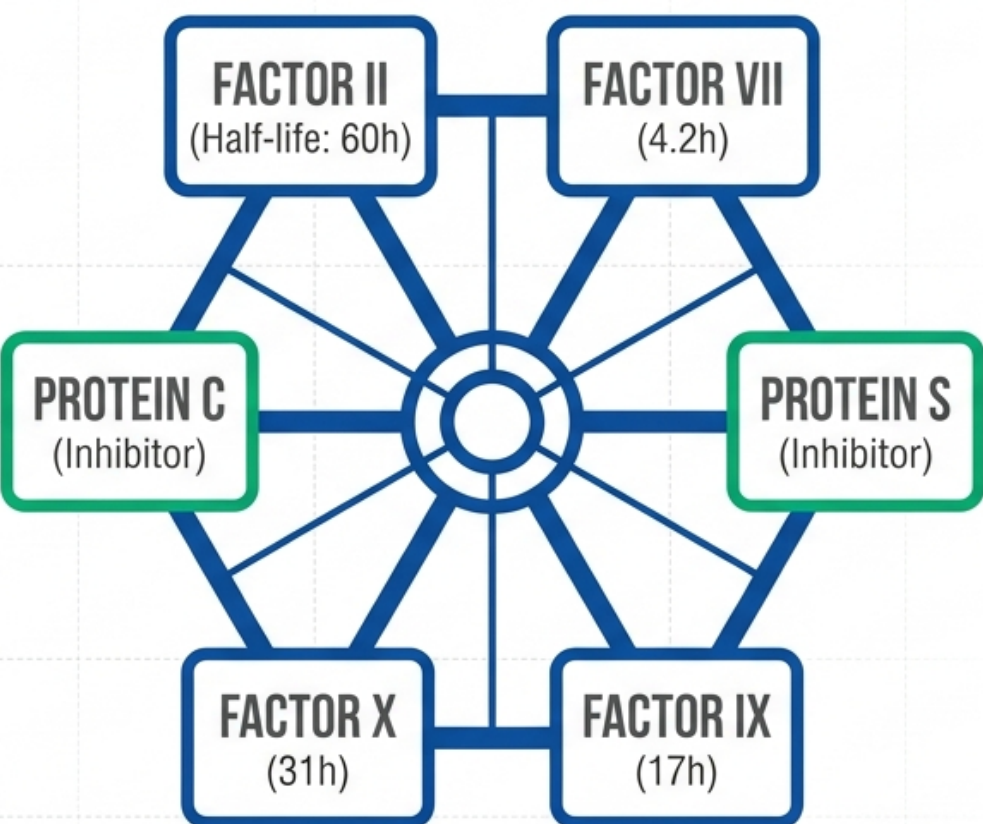
Administration in Neonatal & Pediatric Emergencies

A Clinical Reference Guide & Protocol
Toolkit

Source: The Royal Children's Hospital Melbourne - Beriplex® (Human prothrombin complex) guideline for neonatal and paediatric patients | Augmented with NeoFast Clinical Decision Support tool.



THE COAGULATION CLUSTER



5 MINUTES

Peak plasma concentrations occur within five minutes of infusion.

 Prepared from human plasma. Blood transfusion consent should be sought where possible.

CLINICAL INDICATIONS: STANDARD VS. PEDIATRIC PROTOCOL

Standard CSL Indications

- ✓ Treatment of bleeding due to acquired prothrombin complex deficiency.
- ✓ Reversal of vitamin K antagonists (e.g., warfarin) in perioperative or bleeding contexts.
- ✓ Treatment of VKA overdose.

RCH Specific Indications

- ★ Emergency DOAC reversal (Direct-Acting Oral Anticoagulants).
- ★ Vitamin K Deficiency Bleeding (VKDB) of the newborn.
- ★ Cardiopulmonary bypass bleeding.
- ★ Patient/family refusal of whole blood products.

CRITICAL CAUTIONS & CONTRAINDICATIONS

ABSOLUTE CONTRAINDICATIONS

History of Heparin Induced Thrombocytopenia (HIT)

(Beriplex contains Heparin)

Active Disseminated Intravascular Coagulation (DIC)

(Only consider after resolution of the consumptive state)

Hypersensitivity to product components



CAUTIONS (RISK BALANCING)



Neonates (specifically noted as a caution group)



Patients with a history of thrombosis or prothrombotic state



Presence of a Central Venous Access Device (CVAD)



Patients with liver disease

FOCUS ON NEONATES: VITAMIN K DEFICIENCY BLEEDING (VKDB)

CLINICAL CONDITION

Vitamin K Deficiency Bleeding (VKDB) in infants.

Specifically: major bleeding or refractory to standard treatment.

*In severe cases and very-low-birth-weight infants, delivered vitamin K utilisation may be insufficient due to immature liver function.

CLINICAL THRESHOLD



**Any
INR
 ≥ 1.5**

REQUIRED ACTION



**Beriplex®
50 IU/kg**



**Vitamin K 1mg
(IV or PO)**

**Put on the desired
weight and dose to
get the results in
seconds.**

Dosing Algorithm: Anticoagulant Reversal

CLINICAL CONDITION/SEVERITY	CLINICAL PARAMETERS	RECOMMENDED DOSE
Critical/Major Bleeding (Critical organ/life-threatening on Warfarin OR Major DOAC bleeding)	Any INR ≥ 1.5	50 IU/kg (Max 5000 IU)
Urgent Peri-operative OR Major Bleeding on Warfarin	Pre-treatment INR 2.0 – 3.9	25 IU/kg (Max 2500 IU)
Urgent Peri-operative OR Major Bleeding on Warfarin	Pre-treatment INR 4.0 – 6.0	35 IU/kg (Max 3500 IU)
Urgent Peri-operative OR Major Bleeding on Warfarin	Pre-treatment INR ≥ 6.0	50 IU/kg (Max 5000 IU)

Rules: Based on weight up to 100kg. If >15kg, round to nearest vial size. If ≤ 15 kg, round to nearest 25 IU or 50 IU.

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Medicines

Beriplex® (FACTOR II + FACTOR VII + FACTOR IX + FACTOR X)

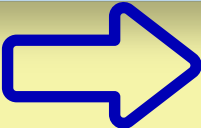
Reversal of direct oral anticoagulants [off-label]

Emergency procedure

Known pre-treatment INR: perioperative treatment and prophylaxis of bleeding during vitamin K+ antagonist therapy.

Reversal of direct oral anticoagulants [off-label]

Choose the indication and fill in with the desired weight and dose to obtain safe calculations in seconds.



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Medicines

Beriplex® (FACTOR II + FACTOR VII + FACTOR IX + FACTOR X)

Emergency procedure

Intermittent IV

250UI/10mL Powder

500UI/20mL Powder

1,000UI/40mL Powder

Weight (kg)

Desired dose (UI/kg)

Preparation & Reconstitution Protocol



1. Presentation

500 IU vials paired with 20 mL water for injection.



2. Reconstitution

Reconstitute using provided diluent and the Mix2Vial™ system. No antimicrobial preservatives—use immediately.

(Multiple vials may be pooled into a single infusion)



3. Critical Constraint

DO NOT further dilute Beriplex®.

Administration Parameters

Absolute Maximums



Maximum Rate:
210 IU/minute



Volume Equivalent:
Approx 8 mL/minute



Strict Infusion Speed Limit

Checklist



Method:
Slow IV push.



Line Requirement:
Must administer via a separate IV line. Do not mix with other medicinal products.



Post-Admin:
Check INR within 30 minutes post-warfarin reversal.

The High-Stakes Calculation Gap

$$\frac{\text{Patient Weight (kg)} \times \text{Target Dose (IU/kg)}}{\text{Reconstituted Concentration (mg/mL)}} = \text{Output Volume}$$

ERROR RISK

The Variables

Calculating exact IU/kg doses while converting to mL based on reconstitution concentration.

The Constraints

Must round to nearest 25/50 IU for neonates.
Must calculate maximum safe infusion rate (3 IU/kg/min).

The Reality

Performing multistep mathematical conversions while managing a critical neonatal bleed introduces an unacceptable risk for human error.

Introducing NeoFast: Precision at the Point of Care



Eliminates manual dosage arithmetic.



Automatically accounts for specific pediatric rounding rules.



Calculates exact reconstitution volumes and safe infusion times instantly.

The image shows a smartphone screen with the NeoFast app. The app has a blue header with the 'neofast' logo. Below the header is a teal bar labeled 'Medicines'. The main interface includes a dropdown menu for 'Beriplex® (FACTOR II + FACTOR VII + FACTOR IX + FACTOR X)', another dropdown for 'Emergency procedure', and a green button labeled 'Intermittent IV'. Below these are three buttons for powder concentrations: '250UI/10mL Powder', '500UI/20mL Powder', and '1,000UI/40mL Powder'. There are also input fields for 'Weight (kg)' and 'Desired dose (UI/kg)'. At the bottom, there is a blue button labeled 'Additional information' with a right arrow, and a link for 'Bibliographical references'. A small note at the very bottom says 'Please note: the information presented in this'.

Step 1: Rapid Clinical Input

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Medicines

Emergency procedure

Intermittent IV

250UI/10mL Powder 500UI/20mL Powder

1,000UI/40mL Powder

Weight (kg)
2

Desired dose (UI/kg)
20

Suggested dose: 20 to 50 UI/kg

Beriplex® (FACTOR II + FACTOR VII ...)
Intermittent IV - 250UI/10mL Powder

Field 1

Procedure Type (e.g., Emergency procedure).

Field 2

Patient Weight (e.g., 2 kg).

Field 3

Desired Dose (e.g., 20 UI/kg). The app provides a safety guardrail by displaying the suggested clinical range (20 to 50 UI/kg) right below the input.

Step 2: Instant, Error-Free Output

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Beriplex® (FACTOR II + FACTOR VII + FACTOR IX + FACTOR X)
Intermittent IV - 250UI/10mL Powder

Dose

Reconstitution

Specific diluent 10mL

Concentration after reconstitution	25mg/mL
Dose after reconstitution	1.6mL
Infusion rate	20min

Note: reconstitute the 250 IU ampoule with a 10 mL diluent to obtain a concentration of 25 UI/mL. The dose shown in mL is after reconstitution. Do not redilute. The maximum infusion rate is 3 UI/kg/min, 1 UI/kg/min has been adopted.



Total Dose: 40 UI

(Automatically calculated for rounding rules).



Reconstitution Formula:

Reconstitute with 10mL to achieve an exact 25mg/mL concentration.



Syringe Draw (Volume): Exactly 1.6 mL to administer.



Safe Infusion Rate: 20 minutes.

(Note: NeoFast adopts a highly conservative 1 UI/kg/min baseline to ensure absolute safety against the 3 UI/kg/min maximum).

Programmed for Complexity

Reversal of direct oral anticoagulants [off-label]

Select the clinical condition and get the results

The screenshot shows the Neofast application interface. At the top is a dark blue header with a hamburger menu icon and the text "neofast". Below this is a teal bar with the word "Medicines". The main content area has a light pink background. It features a dropdown menu currently displaying "Beriplex® (FACTOR II + FACTOR VII + FACTOR IX + FACTOR X)". Below the dropdown is a button labeled "Reversal of direct oral anticoagulants [off-label]". Underneath the button is a search bar. A list of clinical conditions is displayed below the search bar, including "Calculation with the desired factor X: bleeding and perioperative prophylaxis in congenital", "Emergency procedure", "Known pre-treatment INR: perioperative treatment and prophylaxis of bleeding during vitamin K+ antagonist therapy.", and "Reversal of direct oral anticoagulants [off-label]".

NeoFast dynamically adapts its algorithms to align with specific institutional protocols, including off-label DOAC reversal, ensuring instant compliance without flipping through manuals.

The Clinical Summary Cheat Sheet

Neonatal VKDB Focus

INR ≥ 1.5 $\Rightarrow$ 50 IU/kg Beriplex + 1mg Vit K

(Vitamin K dependent bleeding)

Reversal Dosing

INR 2.0-3.9 $\Rightarrow$ 25 IU/kg 

INR 4.0-6.0 $\Rightarrow$ 35 IU/kg 

INR ≥ 6.0 or DOAC $\Rightarrow$ 50 IU/kg 

Admin Rules



Max rate 3 IU/kg/min.



Do NOT further dilute.



Separate IV line required.

The Digital Advantage



Download NeoFast App 

Calculate instantly and safely with NeoFast.

Available in more than 178 countries!

Out now!



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