DOSAGE GUIDE

INSTRUCTIONS FOR USE:

1. Input body weight in window
2. Select initial INR*
3. Read approximate dose recommendations

Note: >100 kg body weight maximum dose. For patients weighing more than 100 kg, the maximum single dose (IU of Factor IX) should therefore not exceed 2500 IU for an INR of 2.0 – 3.9, 3500 IU for an INR of 4.0 – 6.0 and 5000 IU for an INR of > 6.0.

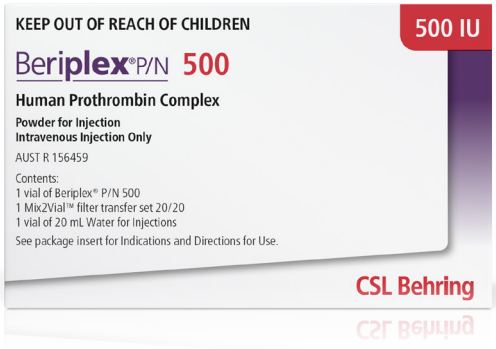
Indication: Treatment and perioperative prophylaxis of bleedings in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required.[1]

Beriplex®
Human Prothrombin Complex

*International Normalised Ratio

Prescribing information can be found on the following page

CSL Behring



Beriplex®

Human Prothrombin Complex

PBS Information: This product is not listed on the PBS. This product is funded under arrangements implemented by the National Blood Authority. Please refer to the National Blood Authority for details.

Before prescribing, please review Product Information
The Product Information can be accessed at www.cslbehring.com.au/au-PI

MINIMUM PRODUCT INFORMATION Beriplex® P/N (Human prothrombin complex) contains factors II, VII, IX & X, proteins C & S. **INDICATIONS:** Treatment and perioperative prophylaxis of bleedings in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required. **CONTRAINDICATIONS:** Hypersensitivity to active substances or excipients; history of heparin-induced thrombocytopenia (HIT); in disseminated intravascular coagulation (DIC), only apply after termination of consumptive state. **PRECAUTIONS:** Risk of thrombosis or DIC, particularly with repeated dosing or in patients with predisposition. Risk of hypersensitivity and HIT type II. Made from human plasma, may contain infectious agents, risk of transmission reduced by donor screening and manufacturing procedures. Use in neonates, children, pregnancy or lactation not established. Consider product heparin content when performing clotting tests. **INTERACTIONS:** Neutralises effect of vitamin K antagonists. **ADVERSE EFFECTS:** Headache, hypotension, thromboembolic events, nausea/vomiting, anaemia, body temperature increased, tachycardia, hypokalemia, insomnia, pleural effusion, atrial fibrillation, skin laceration/subcutaneous haematoma, respiratory distress/dyspnea/hypoxia, fluid overload, diarrhoea, pulmonary oedema. **DOSAGE & ADMINISTRATION:** Initiate treatment under supervision of coagulation disorders specialist. Dose based on algorithm adjusted for patient's body weight, clinical condition and response (approximate dose range 25-50 IU/kg or 1-2 mL/kg); regular monitoring (eg. International Normalised Ratio (INR)) required. Administer intravenously via separate injection/infusion line at maximum rate of 3 IU/kg/min (approximately 8mL/min). Refer to full PI for further information. Contains no preservative, recommended to use immediately after reconstitution. [minPI v2; AU-BAU-0018].

Reference: 1. BERIPLEX® Product Information. For information: CSL Behring (Australia) Pty Ltd: For Medical/Technical Inquiries: Phone 1800 642 865. For Customer Service Inquiries: Phone 1800 063 892. E-mail: customerservice@cslbehring.com.au. Internet: www.cslbehring.com.au. CSL Behring (Australia) Pty Ltd 655 Elizabeth Street, Melbourne, Vic, 3000. ABN: 48 160 734 761. May 2024. AU-BAU-0028. 002239.

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