

## PROTHROMBIN COMPLEX CONCENTRATE (PCC)

### Comparison Table

PRODUCT INFORMATION						
ATTRIBUTES	octaplex® Octapharma			Beriplex® P/N CSL Behring		
Formulation	Freeze dried			Lyophilized		
Diluent	20 mL Water for Injection (WFI)			20 mL Sterile Water for Injection, Ph. Eur.		
Vial Size (nominal)	500 IU			500 IU* *Factor IX is considered the lead factor for potency.		
Administration	Intravenous			Intravenous		
Potency (per vial)	<b>Medicinal Ingredients</b>		<b>octaplex®</b>	<b>Medicinal Ingredients</b>		<b>Beriplex® P/N 500</b>
	Factor II		280 - 760 IU	Factor II		380 - 800 IU
	Factor VII		180 - 480 IU	Factor VII		200 - 500 IU
	Factor IX		500 IU	Factor IX		400 - 620 IU
	Factor X		360 - 600 IU	Factor X		500 - 1020 IU
	Protein C		140 - 620 IU	Protein C		420 - 820 IU
	Protein S		140 - 640 IU	Protein S		240 - 680 IU
Relevant Non-Medicinal Ingredients	Heparin Sodium citrate			Human antithrombin III Heparin Human albumin Sodium chloride and sodium citrate		
Storage	Room Temperature (+2°C to +25°C) Do not freeze. Protect from light.			Room Temperature (up to +25°C) Avoid freezing. Keep product in box during storage.		
Shelf Life	2 years			36 months		
Infusion Rate	Inject the solution intravenously at an initial rate of 1 mL per minute, followed by 2-3 mL per minute, if appropriate.			The reconstituted solution should be administered intravenously (not more than 3 IU/kg/min, max. 210 IU/min, approximately 8 mL/ min).		

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	Initial INR	Approx. dose* (mL octaplex®/kg body weight)	Initial INR	Approx. dose mL/kg body weight	Approx. dose IU (Factor IX)/kg body weight
Recommended Dosage (For normalization of International Normalized Ratio {INR} : ≤ 1.3)	2 – 2.5	0.9 – 1.3	2 – 3.9	1	25
	2.5 – 3	1.3 – 1.6	4.0 - 6.0	1.4	35
	3 – 3.5	1.6 – 1.9	> 6.0	2	50
	> 3.5	> 1.9			
	*The single dose should not exceed 3000 IU (120 mL octaplex®)		It is recommended that the maximum single dose should not exceed 5000 IU of factor IX.		
Indication	Treatment of bleeding and perioperative prophylaxis of bleeding 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.		Indicated in adults (≥ 18 years of age) for the treatment of bleeding and perioperative prophylaxis of bleeding 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.  No adequate study in subjects with congenital deficiency is available.  Beriplex® P/N can be used for the treatment of bleeding and perioperative prophylaxis of bleeding in congenital deficiency of any of the vitamin K dependent coagulation factors only if purified specific coagulation factor product is not available.		
Manufacturing Process	Chromatographic purification of cryo-poor plasma		Cryoprecipitation, Ion exchange chromatography Ammonium sulphate precipitation followed by calcium phosphate adsorption.		
Viral Inactivation/Reduction	Solvent/detergent (S/D) Nanofiltration		Pasteurization Virus filtration		

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Contraindications	For patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.  For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the product monograph.	Known hypersensitivity to any of the components of the product.  For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the product monograph.
Serious Warning and Precautions	This product is prepared from large pools of human plasma, which may contain the causative agents of hepatitis and other viral diseases. The physician should discuss the risks and benefits of this product with the patient prescribing or administering to the patient (see WARNINGS AND PRECAUTIONS – General section of the product monograph).	The use of prothrombin complex concentrates is associated with the risk of thrombosis. Although a rare event, cases of thrombosis have been observed in conjunction with treatment with Beriplex® P/N.  For more details, see WARNINGS AND PRECAUTIONS in the product monograph.
Adverse Reactions (Listed only if more frequently observed than “rarely”. Refer to Product Monograph for complete list.)	There is a risk thromboembolic episodes following the administration of human prothrombin complex.	There is a risk of thromboembolic episodes following the administration of human prothrombin complex.  Undesirable reactions may include the development of heparin-induced thrombocytopenia, type II (HIT, type II)

#### Reference Monographs Approval/Revision Dates

octaplex®	January 10, 2011	Beriplex® P/N	November 05, 2010
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