



PCC- Octaplex®

Four-factor Prothrombin
Complex Concentrate



Storage: +2 to 25° C
Shelf life: 2 years

Do not freeze vials. Store vials in its original package at suggested temperature (preferably 4°C) in order to protect from light. Reconstitute lyophilized powder in provided 20 ml solvent as directed in the package insert. Use immediately after reconstitution.

Contains coagulation factors II, VII, IX and X. Product is prepared from large pools of human plasma by industrial plasma fractionation.

Each vial reconstituted to 20ml contains 500IU FIX and variable concentration of FII, VII and X together with protein C and S.

Indications

- ⊕ Treatment of bleeding and perioperative prophylaxis for bleeding in acquired deficiency of vitamin K dependant coagulation factors, such as in warfarin overdose or when rapid correction of the deficiency is required.
- ⊕ Treatment of bleeding and perioperative prophylaxis in congenital deficiencies of factors II, IX and X.

Contraindications

- ⊕ Hypersensitivity to active substance or to any of the ingredients used in preparation.
- ⊕ Known allergy to heparin or history of heparin induced thrombocytopenia

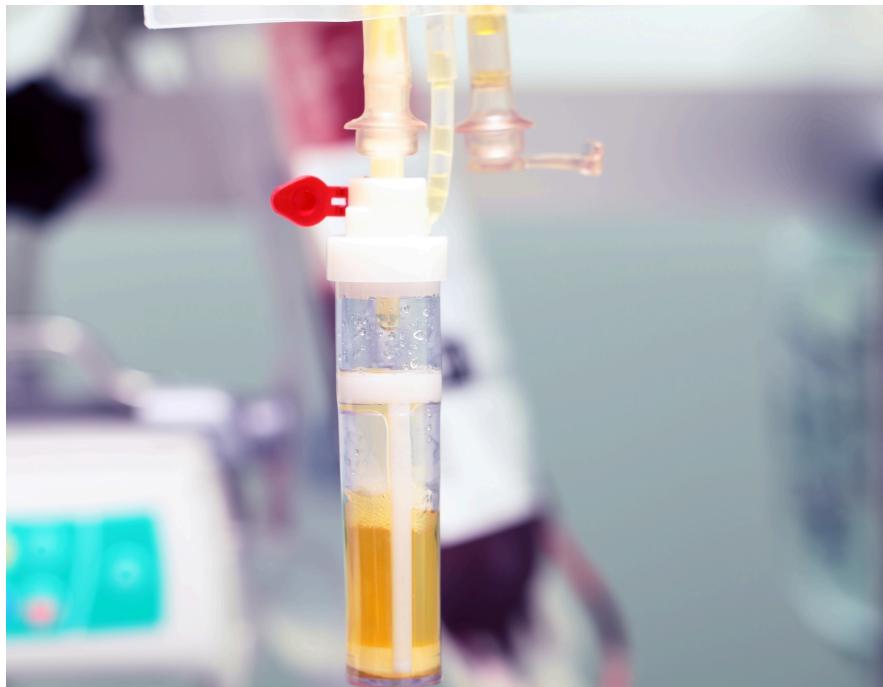
Indications and dosage

Four-factor PCC is currently the recommended factor replacement for management of clinically significant bleeding and for immediate correction of prolonged INR due to anticoagulation from vitamin-K antagonists (i.e. warfarin). There is still however uncertainty with regards to its effectiveness for management of bleeding episodes in patients on rivaroxaban or apixaban. Nonetheless, limited studies do indicate that PCC may have a role to play in such patient groups.

Warfarin withdrawal and vitamin-K (oral or iv.) is sufficient in the majority of cases to correct INR back to therapeutic range. However, where there is significant clinical bleeding or the patient is at high-risk of bleeding, PCC should be considered as the therapeutic option. PCC is delivered as an infusion and rapidly raises FII, VII, IX and X levels within 30 minutes. It is therefore suited for immediate correction of INR when an anti-coagulated patient needs to undergo surgery or an invasive procedure at short notice. PCC has been shown to be superior to FFP in terms of INR correction and mitigation of adverse risks associated with FFP transfusion, such as transfusion transmitted infection, anaphylaxis, TRALI and TACO.

The dose of PCC will depend on the INR before treatment and the targeted INR. As a general guide, 30-50 IU/kg of FIX is sufficient in most patients. The INR correction will be sustained for approximately 6-8 hours. However, the effects of vitamin K, if administered simultaneously are usually achieved within 4-6 hours. Thus, repeated treatment with PCC is not usually required when vitamin K has been administered.

PCC is indicated for management of bleeding and perioperative prophylaxis in patients with congenital deficiencies of coagulation factors II or X. PCC may be considered for management of Haemophilia B patients where the specific FIX concentrate is not readily available. The calculated required dose is based on the empirical finding that approximately 1 IU of FII, IX or X per kg body weight raises the plasma factor II, IX or X activity by 0.02, 0.01 and 0.017 IU respectively. A haematology consult would however be advised for management of such patients.



Administration

- ⊕ Read all instructions in package insert
- ⊕ Reconstitute powder following the instructions carefully
- ⊕ Start infusion at 1 ml/min for first 5 min
- ⊕ If there is no allergic reaction, increase infusion rate by 1 ml/min every 1 to 2 minutes up to a maximum rate of 8 ml/min.
- ⊕ Maximum allowable dose per infusion is 3,000 IU (120 ml)

Nursing observations

	Pre-transfusion vital signs (V/S)?	Stay at patient bedside?		Vital signs during transfusion		Post-transfusion monitoring
		First 5 mins	Remainder of infusion	First 5 mins	Remainder of infusion	
All patients	Yes	Yes		Yes	Every 5 minutes	V/S at completion. Check INR 20-30 min post-infusion.

Adverse reactions and precautions

This product is prepared from human plasma and includes manufacturing processes that reduce viruses by way of a solvent/detergent viral inactivation and a virus removal nanofiltration step. As with any blood product, a potential problem with PCC preparations is the transmission of blood borne pathogens including those of unknown origin. This risk is however considerably lower as compared to non viral-inactivated products which includes FFP.

Due to the procoagulant effects of PCC, the product should not be used in patients with recent myocardial infarction with a high risk of thrombosis or with angina pectoris

unless there is life threatening bleeds due to warfarin overdose or when an emergency surgical procedure is indicated and the INR is above 3. The administration of PCC is also not recommended in the setting of DIC.

Patients given PCC should be observed closely for signs and symptoms of intravascular coagulation or thrombosis, especially in patients at risk of thrombo-embolic complications.

Hypersensitivity reactions may rarely be observed in patients who are allergic to any ingredients in the formulation. The product also contains heparin, and therefore should not be administered to patients suffering from heparin-induced thrombocytopenia. The product is also contraindicated in rare individuals who are IgA deficient and have anti-IgA antibodies.