

Protocol for Rapid reversal of anticoagulation with Warfarin using Prothrombin Complex Concentrate

Treatment Protocol for Octaplex

Octaplex is derived from human plasma which has been virally inactivated. It is a pool product.

Indications	Treatment of bleeding and preoperative 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 the rapid correction of deficiency is required.
Examples of Patients to be considered for Octaplex	<ul style="list-style-type: none"> • Recent abrupt intra-cranial haemorrhage, preferably demonstrated on CT scan. • Haemorrhage with hyperbolic shock (remember all coagulation factors may eventually decline) • Intra ocular bleeding. • Muscle bleed with a compartment syndrome. • Patients requiring emergency surgery who are anticoagulated with warfarin.
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients. Known allergy to heparin or history of Heparin induced thrombocytopenia. There is a risk of thrombosis or disseminated intra vascular coagulation when patients are treated with human prothrombin complex, particularly with repeated dosing. Because of the risk of clotting complications, close monitoring should be exercised, when administering human prothrombin complex to patients with a history of coronary heart disease, liver disease, pre or post operative patients, or patients at risk of thromboembolic events or disseminated intravascular coagulation. In each of these situations the potential benefit of treatment should be weighed against the risk of these complications.
Product Location	<i>Please insert here specific details of the product location within your Trust.</i>

Dosage * As recommended by the company.	Initial INR	2 – 2.5	2.5 - 3	3 – 3.5	>3.5
	Approximate dose ml/kg body weight	0.9 – 1.3	1.3 – 1.6	1.6 – 1.9	>1.9
	Approximate dose IU (factor IX)/kg body weight.	22.5 – 32.5	32.5 - 40	40 – 47.5	>47.5
Vitamin K	Vitamin 5 -10 mg IV should also be given with Octaplex.				
Administration	Please follow companies instructions for preparation of the product. Treatment should be initiated under the supervision of a physician experienced in the treatment of coagulation disorders. Octaplex should be administered intravenously. The infusion should start at a speed of 1ml per minute, followed by 2-3 ml per minute using an aseptic technique. The single dose should not exceed 3000 units for Factor IX (120mls of Octaplex).				
Safety	Octaplex is a virally inactivated product. Measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV. These measures do have a limited value against non-enveloped viruses such as HAV or parvovirus B19. The safety of human prothrombin complex for use in human pregnancy and during lactation has not been established.				
Recommendation	It is strongly recommended that every time Octaplex is administered to a patient, the name and batch number of the product is recorded.				
<p>For more information please see the company's web site</p> <p>http://www.octapharma.com/corporate/</p>					