

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

Treatment Protocol for Beriplex

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

Indications	<p>Treatment of bleeding and preoperative prophylaxis of bleeding in</p> <p>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.</p>
Examples of Patients to be considered for Beriplex	<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	<p>Known hypersensitivity to any of the components of the product. Risk of thrombosis, angina pectoris, recent myocardial infarction (exception life threatening haemorrhages following overdose of oral anticoagulants, and before induction of fibrolytic therapy).</p> <p>In case of disseminated intravascular coagulation prothrombin complex preparation may only be applied after termination of the conceptive state. Known history of Heparin induced thrombocytopenia. 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.</p>
Product Location	<p><i>Please insert here specific details of the product location within your Trust.</i></p>

Dosage *As recommended by the Company.	Initial INR	2.0 - 3.9	4.0 - 6.0	>6.0
	Approximate dose ml/kg body weight	1	1.4	2
	Approximate dose IU (factor IX)/kg body weight.	25	35	50
Vitamin K	Vitamin 5 -10 mg IV should also be given with Beriplex.			
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. Beriplex should be administered intravenously at no more than 3 units per kg per ml (maximum 210 units per ml). The maximum dose should not exceed 5000 IU of Factor IX. The recovery and duration of effect may vary, therefore should be monitored.			
Safety	Beriplex 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 Beriplex is administered to a patient, the name and batch number of the product is recorded.			
For more information please see the company's web site http://www.cslbehring.com/s1/cs/enco/1151443990667/content/1151443991017/home.htm				