PRESCRIBING INFORMATION: octaplex® (human prothrombin complex)
Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Powder and solvent for solution for infusion, available as 500 IU with 20 mL solvent, or 1000 IU with 40 mL solvent. After reconstitution, each vial contains coagulation factors II (14 - 38 IU/mL), VII (9 - 24 IU/mL), IX (18 - 30 IU/mL), Protein C (13 - 31 IU/mL), Protein S (12 - 32 IU/mL) and total protein (13 - 41 mg/mL). FIX specific activity ≥ 0.6 IU/mg proteins.

Indications: Treatment and perioperative prophylaxis of bleeding in 1) acquired deficiency of prothrombin complex coagulation factors when rapid correction of the deficiency is required, and 2) congenital deficiency of the vitamin K dependent coagulation factors II and X when purified specific coagulation factor product is not available.

Dosage and Method of Administration: Treatment should be initiated under the supervision of a physician experienced in the treatment of coagulation disorders. The dosage and duration of substitution therapy depends on the severity of the coagulation disorder, location and extent of bleeding, half-life of the different coagulation factors and patient’s clinical condition. Regular determination of either individual plasma levels of coagulation factors or global tests of prothrombin complex levels (prothrombin time, INR) are needed for dosing. Guidance for bleeding and bleeding prophylaxis during vitamin K antagonist treatment: Dose will depend on INR before treatment and target INR. Prothrombin complex factor correction persists for approximately 6 - 8 hours. Guidance for initial dosage for congenital deficiency: Required units for factor X deficiency = body weight (kg) x desired factor X rise (IU/mL) x 59. Required units for factor II deficiency = body weight (kg) x desired factor II rise (IU/mL) x 50. For intravenous administration only. Start infusion rate at 1 mL/min followed by 2 - 3 mL/min.

Contraindications: Hypersensitivity to active substance, excipients or heparin. History of heparin induced thrombocytopenia.

Special Warnings and Precautions: The advice of a specialist experienced in management of coagulation disorders should be sought. Infusion of prothrombin complex may exacerbate underlying hypercoagulable state in patients receiving vitamin K antagonists. Stop infusion if allergic or anaphylactic-type reactions occur. Despite measures to prevent infection, possibility of infective transmission cannot be totally excluded - record patient name and product batch number. Appropriate vaccination (hepatitis A and B) is recommended for patients in regular/repeated receipt of human plasma-derived prothrombin complex products. Repeated dosing in patients with congenital or acquired bleeding defect is associated with a risk of thrombosis or disseminated intravascular coagulation (DIC). Closely monitor when administering to patients with a history of coronary heart disease or liver disease, to peri- or post-operative patients, to neonates, and to patients at risk of thrombosis or DIC. octaplex® contains sodium at 75 – 125 mg per 500 IU vial, and 150 – 250 mg per 1000 IU vial; this should be taken into consideration in patients on controlled sodium diets. Only use in pregnancy and lactation if clearly indicated.

Undesirable effects: Rare (≥1/10,000 to <1/1,000) formation of circulating antibodies inhibiting one or more of the human prothrombin complex factors, which will manifest itself as a poor clinical response; allergic or anaphylactic-type reactions; increase in body temperature; headache; transient increase in liver transaminases; octaplex® contains heparin, which may cause a sudden allergy-induced reduction in thrombocytes. Refer to the SmPC for other adverse reactions.

Legal Category: POM. Packaging quantities and Basic NHS cost: 500 IU £208.25 (UK); 1000 IU £416.50 (UK). Marketing Authorisation Number: 500 IU PL 10673/0027 (UK), PA 521/13/1 (RoI); 1000 IU PL 10673/0041 (UK), PA 521/13/2 (RoI). Additional information is available on request from the Marketing Authorisation Holder: Octapharma Ltd, The Zenith Building, 26 Spring Gardens, Manchester, M2 1AB, United Kingdom.

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UK: Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Octapharma by telephoning 0845 1300 522.

Republic of Ireland: Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to Octapharma by telephoning 1890 920 522.