Follow the hospital's aseptic procedures at all times. Working on a clean flat surface, remove the vials from the outer packaging and remove the flip top lids. Disinfect the vial injection sites with an alcohol swab.

**Step 1**
Remove the top of the Mix2Vial™ package. Do not remove the device from the package.

**Step 2**
Seat the blue end of the device on the water vial, using the blister pack as a holder. Push down until the spike penetrates the stopper and the device snaps in place.

**Step 3**
Remove the plastic package and discard it. Take care not to touch the exposed end of the device.

**Step 4**
Turn the water vial upside down and insert the clear end into the powdered octaplex® vial, pushing down until the spike penetrates the stopper and the device snaps in place.

**Step 5**
The water will automatically flow into the octaplex® vial. Gently swirl the vial to make sure the octaplex® is thoroughly mixed.

**Step 6**
Remove the water vial by turning it anticlockwise. Attach a syringe to the octaplex® vial.

**Step 7**
Turn the octaplex® vial upside down and withdraw the solution into the syringe. Remove the syringe by turning the barrel counter clockwise. octaplex® is now ready for administration.

The reconstitution guidelines above have been adapted from octaplex® Summary of product characteristics and reconstitution direction from Mix2Vial™ of West Pharmaceutical Services.
Abbreviated Prescribing Information octaplex® (500 IU coagulation factor IX per vial, powder and solvent for infusion, Human Prothrombin Complex)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Powder and solvent for solution for infusion. Each vial contains coagulation factors II (280 - 760 IU), VII (180 - 480 IU), IX (500 IU) and X (360 - 600 IU), Protein C (260 - 620 IU), Protein S (240 - 640 IU) and total protein (260 - 820mg). 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:** 1 IU/kg body weight raises the activity of factor II by 0.02 IU/ml and factor X by 0.017 IU/ml. 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. Stop infusion if allergic or anaphylactic 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. Infusion of prothrombin complex may exacerbate underlying hypercoagulable state in patients receiving vitamin K antagonists. 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 75 - 125 mg sodium per vial and this should be taken into consideration in patients on controlled sodium diet. Only use in pregnancy and lactation if clearly indicated. **Undesirable Effects:** Risk of thromboembolic episodes. Headache, transient rise in liver transaminases, allergic or anaphylactic - type reactions including increase in body temperature may occur rarely. Replacement therapy may rarely lead to inhibitor formation manifesting as poor clinical response. octaplex® contains heparin therefore sudden allergy induced thrombocytopenia may occur. For further information on side effects please refer to SmPC. **Legal category:** POM Marketing Authorisation Numbers: PL 10673/0027 (UK); PA 521/13/1 (ROI) **Package Quantities and Basic NHS Cost:** Vial containing 500 IU Factor IX: £245 (UK)

Further information is available from the Marketing Authorisation Holder: Octapharma Limited, The Zenith Building, 26 Spring Gardens, Manchester, M2 1AB. United Kingdom. **Date of Preparation:** September 2013 OPX/13/11

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or [www.imb.ie](http://www.imb.ie). Adverse events should also be reported to Octapharma on +44 (0)1748 828855.