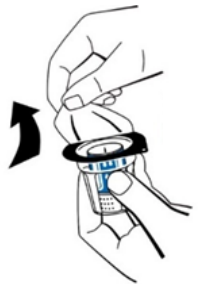
octaplex®
Prothrombin Complex Concentrate
1000 & 500 IU Vials

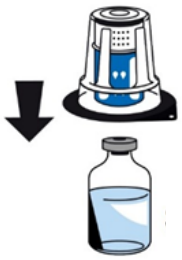
Reconstitution Instructions

Prepare at room temperature and on a stable surface



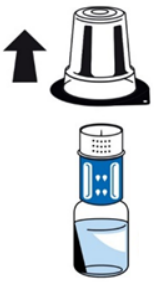
1

Remove the flip caps on the lyophilized powder and solvent vials and disinfect the rubber stoppers with an alcohol swab and allow to dry. Open the Nextaro® transfer device package by peeling off the lid. To maintain sterility, do not remove it from the blister package and do not touch the spike.



2

Place the solvent vial on a flat, even, clean surface and hold it firmly. Without removing the blister package, place the blue part of the Nextaro® on top of the solvent vial and press straight and firmly down, in one swift motion, until it snaps into place. **Do not twist while attaching.**

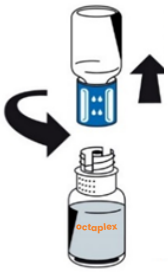


3

While holding onto the solvent vial, carefully remove the blister package by pulling vertically upwards. Make sure to leave the transfer device attached firmly to the solvent vial

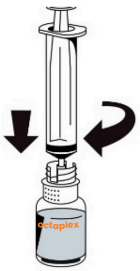
4

Take the solvent vial with Nextaro® attached and turn it upside down. Place the white part of the transfer device connector on top of the powder vial and press firmly down, in one swift motion, until it snaps into place. **Do not twist while attaching.** The solvent will flow automatically into the powder vial.



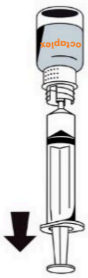
5

Gently swirl the product vial until the product is fully dissolved, do not shake the vial. Unscrew the Nextaro® transfer device counterclockwise into two parts. Do not touch the luer lock connector.



6

Attach a syringe to the luer lock outlet on the white part of the transfer device.



7

Turn the vial upside down and draw the solution into the syringe.

8

Once the solution has been transferred, firmly hold the barrel of the syringe (keeping the syringe plunger facing down) and remove the syringe from the transfer device. Dispose of the white part of the transfer device together with the empty vial.

Attach a suitable administration set to the luer adapter of the syringe.

Disinfect the intended injection site appropriately.

Using an aseptic technique, inject the octaplex® solution intravenously at an initial rate of 1 mL per minute, followed by 2-3 mL per minute, if appropriate. A pump can be used to regulate and control the injection rate when administering octaplex®. No blood should enter the syringe due to the risk of fibrin clot formation.

Any unused product or waste material should be disposed of immediately

Reference: Octaplex® Product Monograph, Octapharma Canada, 21 November 2024

Strength	Vial Size	Volume of Solvent to be Added to Vial	Approximate Available Volume	Concentration per mL
500 IU	30 mL	20 mL	20 mL	25 IU/mL FIX
1000 IU	50 mL	40 mL	40 mL	

IU = International units; FIX = Human Coagulation Factor IX

Administration Instructions	
Description	octaplex® is a human prothrombin complex (PCC) containing the coagulation factors II, VII, IX, and X and Proteins C and S. It is virus reduced by the way of a solvent/detergent (S/D) two-step viral inactivation process and a viral removal nanofiltration step.
Indications and Clinical Use	octaplex® (Human Prothrombin Complex) is indicated for the treatment of bleeding and perioperative 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 rapid correction of the deficiency is required.
Contraindications	octaplex® is contraindicated for patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. • Since octaplex® contains up to 310 IU of heparin, it should not be given to patients suffering from heparin-induced thrombocytopenia type II or with known allergies to heparin. Even if the antibody against the heparin-protein complex cannot be demonstrated, the administration of octaplex® may cause a booster effect with an immediate generation of the antibody. • octaplex® is contraindicated in those rare cases where an individual has an immunoglobulin A (IgA) deficiency, with known antibodies against IgA. • octaplex® should not be used in patients with recent myocardial infarction, with a high risk of thrombosis, or with angina pectoris with the exception of life-threatening bleeds due to overdose of oral anticoagulants, or when an emergency surgical procedure is indicated in patients on vitamin K antagonists and an INR (International normalised ratio) > 3. • In patients suffering from disseminated intravascular coagulation (DIC), the administration of octaplex® is principally not recommended because of the pro-coagulant capacity of the product. However, for life-threatening events when the substitution by FFP is not sufficient enough or if FFP cannot be given because of a threat of hypervolaemia, octaplex® might be used after interrupting the cause of DIC. Under these circumstances, it is important to administer antithrombin (AT) and heparin before the administration of a PCC. • In patients treated for coagulation disorders because of chronic liver disease or because of liver transplantation, AT levels should be monitored and an AT concentrate should be given concomitantly if an AT deficiency is present. No clinical data are available for octaplex® for the treatment of bleeding disorders because of liver parenchymal disorders or oesophageal varices or because of major liver surgery therefore octaplex® cannot be recommended in these patients
Storage	Store the product between 2°C to 25°C. Do not freeze. Protect from exposure to light. Unopened vials have a shelf-life of up to 3 years. After reconstitution the solution is to be used immediately. However, if it is not administered immediately, the reconstituted solution can be stored for up to 8 hours at 2°C to 25°C, provided sterility of the stored product is maintained.

Reference: Octaplex® Product Monograph, Octapharma Canada, 21 November 2024