

Please read all steps thoroughly before proceeding.



1 Disinfect the rubber stoppers.



2 Remove Mix2Vial™ cover.



3 Firmly press blue end onto water vial.



4 Remove plastic packaging.



5 Holding the octaplex® vial on a flat surface, firmly press the transparent end onto the octaplex® powder vial.



6 **MAINTAIN PRESSURE** until there is a complete transfer of water into the powder vial.



7 With both vials still attached, slowly swirl (to prevent formation of bubbles) the octaplex® vial to ensure the product is fully dissolved to a clear or slightly opalescent solution.



8 After dilution, **UNSCREW THE TWO PARTS** of the Mix2Vial™ by holding the blue and transparent parts.



9 The transparent part must stay on the octaplex® vial, as it contains the **FILTER** (15µ).



10 Attach a plastic sterile disposable 20 mL syringe to the transparent part of Mix2Vial™.



11 Invert the system and draw the reconstituted octaplex® into the syringe.

Administration Instructions

Administration	<ul style="list-style-type: none"> • octaplex® should be administered intravenously. • Ideally, a new, clean IV line should be used. Otherwise, the IV line must first be 'cleaned' of other products by flushing it with a saline or dextrose 5% solution. octaplex® should not be mixed with any other product (including saline or dextrose 5% solution) in the IV line. • Must be administered immediately after reconstitution.
Rate of administration	<ul style="list-style-type: none"> • The infusion should start at a speed of 1 mL per minute (60mL/hour), followed by 2-3 mL per minute (120-180mL/hour), using aseptic technique.
Incompatibility	<ul style="list-style-type: none"> • octaplex® should not be mixed with other medication in the same infusion set.
Vital signs	<ul style="list-style-type: none"> • The patient's pulse rate should be measured before and during the injection. If a marked increase in the pulse rate occurs, the injection speed must be reduced or the administration must be interrupted.



octapharma

For the safe and optimal use of human proteins

What the medication is used for:

- 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.

What it does:

- The administration of octaplex® can temporarily stop bleeding in patients with deficiency of one or several of the coagulation factors II, VII, IX and X, which are commonly called the Prothrombin Complex. octaplex® will start working immediately upon injection. octaplex® should only be used when rapid correction of major bleeding or emergency surgery is warranted.

When it should not be used:

- If reduction of the dose of the vitamin K antagonist and/or administration of vitamin K is sufficient.
- octaplex® is not for patients who are hypersensitive to this drug or to any ingredient in the formulation, such as heparin, or component of the container.
- octaplex® should not be used in patients with a recent heart attack, with a high risk of blood clots, or with coronary artery disease, or chronic liver disease.

What the medicinal ingredients are:

- Human Coagulation Factor II, VII, IX and X, and Proteins C and S.

What the important non-medicinal ingredients are:

- Heparin, sodium citrate, solvent (Water for Injection).

Notes