Prepare at room temperature and on a stable surface.

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.

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

8. The transparent part must stay on the octaplex® vial, as it contains the FILTER (15µ).
9. Attach a plastic sterile disposable 20 mL syringe to the transparent part of Mix2Vial™.
10. Invert the system and draw the reconstituted octaplex® into the syringe.

**Administration Instructions**

**Administration**
- 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**
- 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**
- octaplex® should not be mixed with other medication in the same infusion set.

**Vital signs**
- 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.
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).