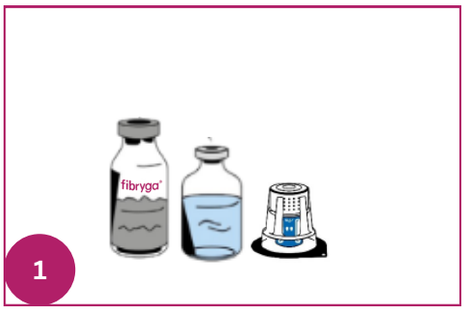
fibryga®

Fibrinogen Concentrate (Human) Powder
for Solution for Injection / Infusion, 1 g/vial

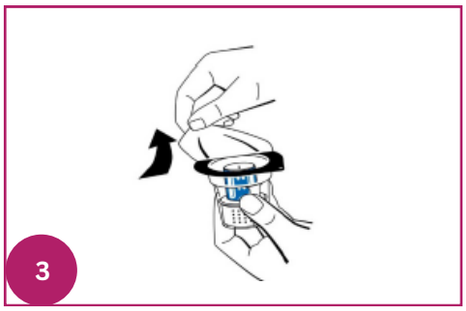
Reconstitution Instructions

Ensure the fibryga vial and the water for injection are at room temperature

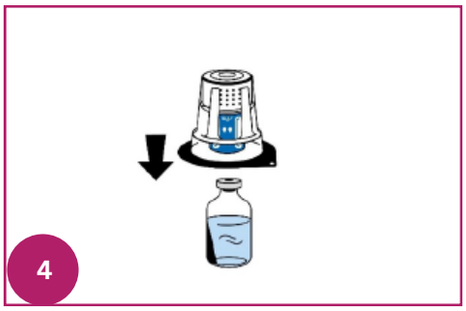


Lay out the fibryga® kit contents on a clean flat surface. You will need a 50mL syringe.

Remove the plastic caps and discard. Clean the rubber stoppers with an alcohol swab and allow them to dry.



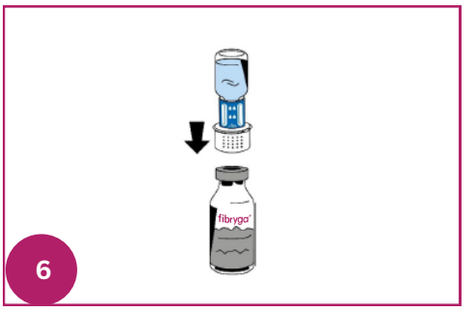
Peel off the lid on the nextaro® transfer device package without removing it from the blister package and do not touch the spike.



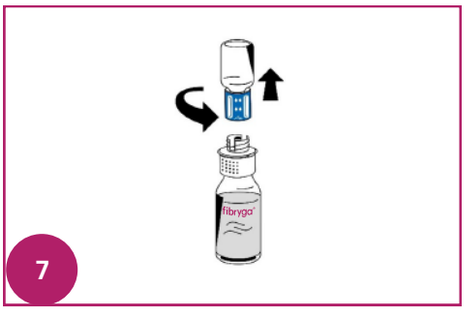
Place the solvent vial on an even, clean surface and hold it firmly. Place the blue part of the nextaro® on top of the solvent vial. Press straight and firmly down until it snaps into place. Do not twist while attaching.

The transfer device must be attached to the solvent vial first and then to the powder fibryga® bottle to prevent loss of vacuum and failure to transfer.

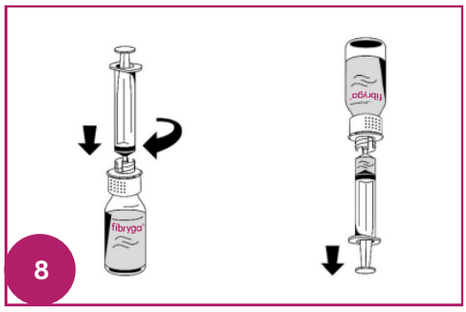
While holding onto the solvent vial, carefully remove the blister package from the nextaro® by pulling vertically upwards. Make sure to leave the nextaro® attached firmly to the solvent vial.



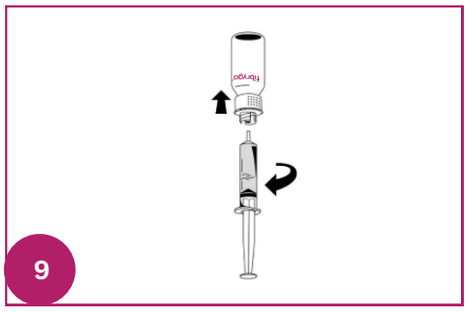
Place the powder fibryga® bottle on an even, clean surface and hold it firmly. Take the solvent vial with the attached nextaro® and turn it upside down. Place the white part of nextaro® connector on top of the fibryga® bottle and press firmly down until it snaps into place. Do not twist while attaching. The solvent will flow automatically into the fibryga® bottle.



After reconstitution is complete, unscrew the blue part of nextaro® (counterclockwise) into two parts. Discard the empty solvent vial along with the blue part of nextaro®. Do not touch the Luer lock connector on the white part of nextaro®.



Carefully attach a syringe to the Luer lock connector on the white part of nextaro®. Turn the fibryga® bottle upside down and draw the solution into the syringe.



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 nextaro® device. Dispose of the white part of nextaro® together with the empty fibryga® bottle.

Vial Size	Volume of WFI to be added to vial	Approximate Available Volume	Nominal Concentration per mL
1g	50 mL	50 mL	20 mg

Administration Instructions	
Description	Fibryga® (Fibrinogen Concentrate (Human), 1 g/vial) is a sterile, freeze dried preparation of highly purified fibrinogen. Fibryga® is prepared from large pools of human plasma employing precipitations, filtrations and chromatographic steps. Pathogen inactivation/removal is accomplished by a solvent detergent (S/D) method and nanofiltration (20 nm).
Indications and Clinical Use	Fibryga® is indicated for the treatment of acute bleeding episodes and perioperative prophylaxis in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia. Fibryga® may be used as a complementary therapy during the management of uncontrolled severe bleeding in patients with acquired fibrinogen deficiency in the course of surgical interventions.
Contraindications	Fibryga® is contraindicated in individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis to fibryga® or its components.
Storage	Fibryga® can be stored at +2°C to +25°C for up to 36 months from the date of manufacture. Do not use product after expiry date. Stability of the reconstituted solution has been demonstrated for up to 24 hours at + 25°C. Discard partially used vials. Do not freeze. Protect from exposure to light. Keep in a safe place out of the reach and sight of children.
Dosage For detailed dosing instructions see the fibryga® Product Monograph	**Congenital Afibrinogenemia and Hypofibrinogenemia** The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding or minor surgery and 150 mg/dL for major bleeding or major surgery. Fibryga® dose when baseline fibrinogen level is known Dose should be individually calculated for each patient based on the target plasma fibrinogen level based on the type of bleeding, actual measured plasma fibrinogen level and body weight, using the following formula: $\text{Dose (mg/kg body weight)} = \frac{\text{[Target level (mg/dL) - measured level (mg/dL)]}}{\text{1.8 (mg/dL per mg/kg body weight)}}$ **Fibryga® dose when baseline fibrinogen level is not known** If the patient's fibrinogen level is not known, the recommended dose is 60 mg per kg of body weight administered intravenously. Monitoring of patient's fibrinogen level is recommended during treatment with fibryga®. **Acquired Fibrinogen Deficiency** The recommended initial dose for patients with uncontrolled severe bleeding in the course of surgical interventions is 4 g. Additional doses of 4 g are to be administered as needed to bleeding patients when fibrinogen plasma level is ≤200 mg/dL or FIBTEM A20 is ≤12 mm (or equivalent values generated by other thromboelastometry/thrombelastography methods). Monitor the patient's fibrinogen plasma level or the clot firmness of the fibrin-based clot during treatment with fibryga®.

Reference 1: Fibryga® Product Monograph. Octapharma 24 October 2024