Fibrinogen concentrate is the preferred choice for fibrinogen replacement in congenital fibrinogen deficiency[2]

fibryga®
Fibrinogen (Human)

- Sterile, freeze-dried preparation of highly purified fibrinogen
- Prepared from large pools of human plasma screened via serologic and nucleic acid tests
- Undergoes 2-step process for viral inactivation (solvent/detergent) and removal (nanofiltration)
- Rapid reconstitution
- Convenient transfer device with protective vacuum seal (Octajet®)

Important Use Information

- Do not use fibryga® beyond the expiration date.
- Use aseptic technique when preparing and reconstituting fibryga®.
- Inspect the reconstituted fibryga® solution in the syringe for visible particulate matter and discoloration prior to administration. The reconstituted solution should be almost colorless and slightly opalescent. Do not use if particulate matter or discoloration are observed.
- The powder should be reconstituted only directly before injection.
- After reconstitution, do not refrigerate or freeze the fibryga® solution. Use the reconstituted fibryga® solution immediately or within 4 hours after reconstitution.
- Discard any remaining fibryga® solution.

Indications and Usage
Fibryga® is a human fibrinogen concentrate indicated for the treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.

Fibryga® is not indicated for dysfibrinogenemia.

Important Safety Information
Fibryga® is contraindicated in individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis, to fibryga® or its components. The most serious adverse reactions that may be observed for fibryga® are thromboembolic episodes and anaphylactic type reactions. The most common adverse reactions observed in more than one subject in clinical studies with fibryga® (>5% of subjects) were vomiting, weakness and pyrexia (fever).

Note: Use aseptic technique when preparing and reconstituting fibryga®. The powder should be reconstituted only directly before injection.[1]

Please see enclosed Full Prescribing Information.

RECONSTITUTION GUIDE

Indications and Usage
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Note: Use aseptic technique when preparing and reconstituting fibryga®. The powder should be reconstituted only directly before injection.[1]

Please see enclosed Full Prescribing Information.

References: 1. Fibryga®, Fibrinogen Concentrate (Human) Prescribing Information. Hoboken, NJ: Octapharma USA Inc.; June 2017. **2.** Lissitchkov T, Madan B, Djambas Khayat C, et al. Efficacy and safety of a new human fibrinogen concentrate in patients with congenital fibrinogen deficiency: an interim analysis of a Phase III trial. Transfusion. 2018;58(2):413-22.

Date of preparation: 6/2018. FIBR-0103-POT

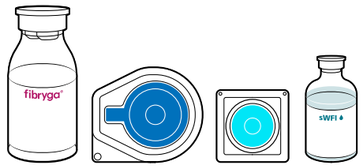
octapharma®
For the safe and optimal use of human proteins

fibryga®
Fibrinogen (Human)

PART 1: PREPARATION

1 The fibryga® package contains:

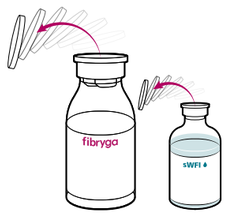
- 1 single-use bottle of fibryga® concentrate
- 1 transfer device (Octajet)
- 1 particle filter



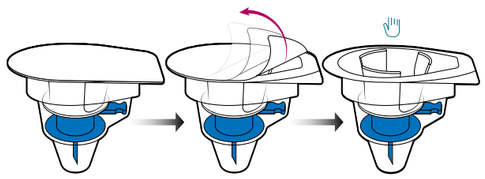
50 mL of sterile Water for Injection (sWFI) should also be used for the Reconstitution.[1]

2 Warm both the powder and sWFI in their closed bottles to room temperature. If a water bath is used, prevent water from coming into contact with rubber stoppers or caps of bottles. The temperature of the water bath should not exceed 37°C (98°F).

3 Remove the caps from the fibryga® and sWFI bottles to expose the central portion of the rubber stoppers. Clean the rubber stoppers with an alcohol swab and allow the rubber stoppers to dry.[1]



4 Peel away the lid of the outer package of the Octajet transfer device, leaving it in the clear outer package to maintain sterility.[1]



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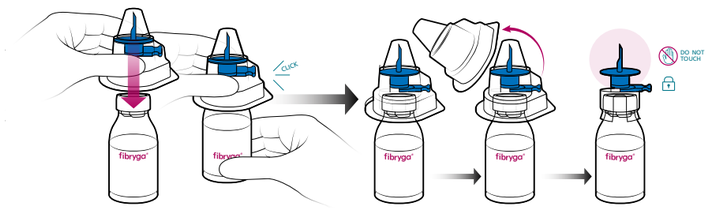
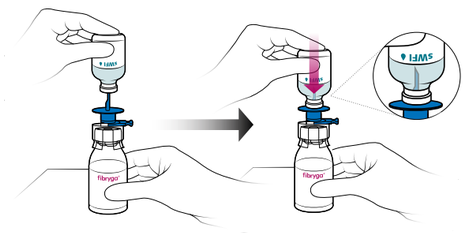
Please see enclosed Full Prescribing Information.

PART 2: ASSEMBLY

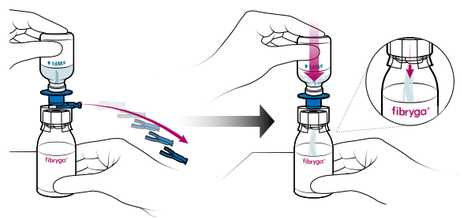
1 Take the Octajet in its outer package and invert it over the fibryga® bottle, pushing it down until the clips are locked. While holding onto the fibryga® bottle, carefully remove the outer package from the Octajet. Be careful not to touch the blue water spike, and leave the Octajet attached firmly to the fibryga® bottle.[1]



2 With the fibryga® bottle held firmly on a level surface, invert the sWFI bottle and place it at the center of the water spike. Push the blue plastic cannula of the Octajet firmly through the rubber stopper of the sWFI bottle.[1]



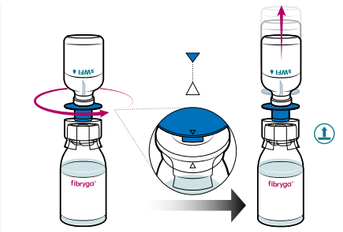
3 Remove the distance ring and press the sWFI bottle down. sWFI will flow into the fibryga® bottle.[1]



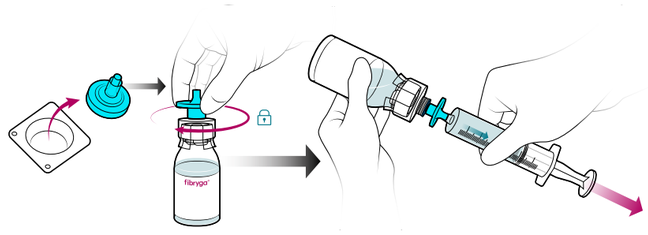
PART 3: MIXING AND TRANSFER TO SYRINGE

1 When transfer of the sWFI is complete, gently swirl the fibryga® bottle until the powder is fully dissolved. To avoid foam formation, do not shake the bottle. The powder should be dissolved completely within approximately 5 to 10 minutes.[1]

2 Turn the blue sWFI bottle connector in either direction to bring the position markers together, and remove the sWFI bottle together with the water spike. Keep the fibryga® bottle upright to avoid leaking.[1]



3 Firmly connect the provided particle filter on the remaining Luer Lock on the fibryga® bottle, and withdraw the solution through the particle filter into a syringe. Detach the filled syringe from the particle filter and discard the empty bottle and filter.[1]



Please see Important Safety Information throughout.