Fibryga

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Fibrinogen Concentrate	None

PREPARATION and ADMINISTRATION

Fibryga is a plasma derived factor concentrate, blood consent IS required.

Reconstitution

Diluent: Water for injection (50 mL)

See pages 3-5 for reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter prior to administration

IV Direct	Intermittent Infusion	Continuous Infusion
Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Administer slowly at a recommended maximum 5 mL/min, for patients with congenital afibrinogenemia and hypofibrinogenemia, and at a recommended maximum rate of 20 mL/min during the management of uncontrolled severe bleeding in the course of surgical interventions for patients with acquired fibrinogen deficiency.	**IV Bag (large volume pump)**	**IV Bag (large volume pump)**
	Congenital afibrinogenemia and hypofibrinogenemia – Administer slowly at a recommended maximum 5 mL/min (300 mL/h) Management of uncontrolled severe bleeding in the course of surgical interventions for patients with acquired fibrinogen deficiency – administer at a recommended maximum rate of 20 mL per minute (1200 mL/h)	Not applicable
	Syringe (syringe pump)	**Syringe (syringe pump)**
	Congenital afibrinogenemia and hypofibrinogenemia – Administer slowly at a recommended maximum 5 mL/min (300 mL/h) Management of uncontrolled severe bleeding in the course of surgical interventions for patients with acquired fibrinogen deficiency – administer at a recommended maximum rate of 20 mL per minute (1200 mL/h)	Not applicable

Requirements and Monitoring

Watch for potential allergic or thrombic events.

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Document all vitals taken.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Fibrinogen Concentrate	None

INDICATIONS

Indicated for:

- The treatment of perioperative prophylaxis in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia.
- The treatment of acute bleeding episodes in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia.

ADVERSE EFFECTS

Allergic-type hypersensitivity reactions including anaphylaxis have been reported but are rare. They can manifest as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue. Adverse events identified in clinical trials included sepsis, cerebrovascular accident, cardiac tamponade, hemorrhage, respiratory failure, acute kidney injury, renal failure, hallucinations, tachycardia, pleural effusion, pyrexia, diarrhea, headache, nasopharyngitis and other respiratory tract infections and muscle pain.

If an AE is suspected: stop the infusion, disconnect and cap the i.v. tubing if infusing via pump, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume infusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

For patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system

Recommended Dose and Dosage Adjustment in 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.

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Fibrinogen Concentrate	None

COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

- None

LIBRARIES

- Searchable Drug Library Document

RECONSTITUTION

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

1. Warm both the powder (FIBRYGA) and the solvent (Water for Injection) in unopened bottles up to room temperature. This temperature should be maintained during reconstitution. Don clean gloves.

2. Remove the cap from the powder (FIBRYGA) bottle and the solvent to expose the central portion of the infusion stopper. Clean the rubber stoppers of both bottles with an alcohol swab and allow the rubber stoppers of the bottles to dry.

3. Peel away the lid of the outer package of the Octajet transfer device. To maintain sterility, leave the Octajet device in the clear outer packaging.

4. Take the Octajet in its outer package and invert it over the powder (FIBRYGA) bottle. Place device while in the outer package onto the center of the powder bottle until the clips of the product spike (colorless) are locked. While holding onto the powder bottle, carefully remove the outer package from the Octajet, being careful to not touch the water spike (blue) and leave the Octajet attached firmly to the FIBRYGA bottle (Fig. 1).

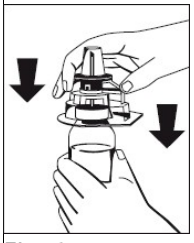

Fig. 1

CLASSIFICATION	ALERTS
Fibrinogen Concentrate	None

5. With the powder (FIBRYGA) bottle held firmly on a level surface, invert the solvent bottle and place it at the center of the water spike. Push the blue plastic spike of the Octajet firmly through the rubber stopper of the solvent bottle (Fig. 2).

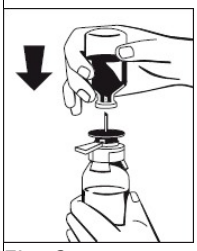

Fig. 2

6. While stabilizing the solvent bottle, remove the distance ring (Fig. 3). Press the solvent bottle down (Fig. 4). Solvent will flow into the powder (FIBRYGA) bottle.

Fig. 3

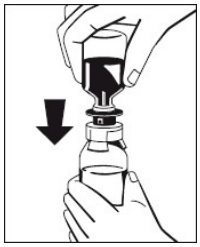

Fig. 4

7. When transfer of the solvent is complete, gently swirl the product bottle until the powder is fully dissolved. Do not shake the bottle to avoid foam formation. The powder should be dissolved completely within approximately 5 minutes. It should not take longer than 30 minutes to dissolve the powder.

8. Turn the blue solvent bottle connector (both directions possible) to bring position markers together and remove solvent bottle together with the water spike (Fig. 5).

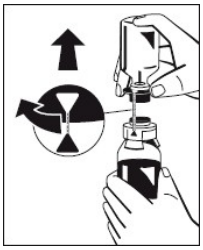

Fig. 5

9. While holding the provided filter in its outer package, attach a syringe to the filter (Fig. 6) and then connect the filter to the Octajet Luer Lock on the powder bottle (Fig. 7). Withdraw the solution through the filter into the syringe (Fig. 8).

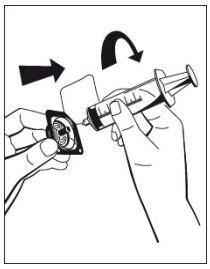

Fig. 6

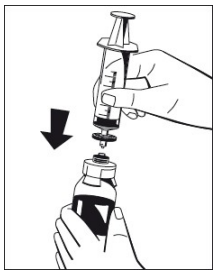

Fig. 7

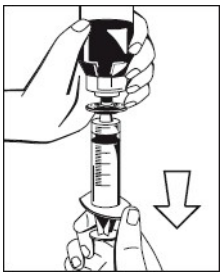

Fig. 8

CLASSIFICATION	ALERTS
Fibrinogen Concentrate	None

10. Detach the filled syringe from the filter and discard the empty bottle and used filter.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Fibryga product monograph. Found at https://www.octapharma.com/products/product-overview