FIBRYGA™ Fibrinogen Concentrate

APPLICABILITY: This document applies to AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***OTHER NAMES:*** *Fibrinogen Concentrate (Human)* ***Company: Octapharma*** ***Class:*** *Manufactured blood product (human)*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**Intermittent Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**
**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration.**

DESCRIPTION OF PRODUCT:

- A sterile, freeze dried preparation of highly purified fibrinogen prepared from large pools of human plasma.
- Contains 1 g fibrinogen per vial.
- Fibrinogen concentrate is considered interchangeable with the blood component cryoprecipitate.
- After reconstitution with 50 mL sterile water for injection (provided separately with product), fibrinogen concentration in each vial will be approximately 20 mg/mL.
- Pathogen inactivation/removal performed via solvent/detergent (S/D) method and nanofiltration.
- Also contains glycine, L-arginine hydrochloride, sodium chloride, and sodium citrate dehydrate.
- Latex free

AVAILABILITY:

- Supplied by Canadian Blood Services.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Treatment of acute bleeding episodes and perioperative prophylaxis in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia.
- Prophylaxis in acute promyelocytic leukemia/chemotherapy (<1.5g/L)
- In a bleeding patient when:
  - Fibrinogen is less than 1.5g/L (2.0g/L in obstetrical hemorrhage or cardiovascular surgery)
  - Abnormal ROTEM or TEG result is suggestive of hypofibrinogenemia/fibrinolysis
  - The clinical status of the patient is highly suggestive of hypofibrinogenemia/dysfibrinogenemia, and the urgency of the situation does not allow to wait for fibrinogen levels.

CONTRAINDICATIONS:

- Patients who are hypersensitive (allergic) to this blood product or any ingredient in its formulation (see description of product)

WARNINGS:

- Risk of thrombosis in patients with congenital deficiency exists, particularly when treated with high doses or repeated dosing. Patients receiving FIBRYGA™ should be monitored for signs and symptoms of thrombosis.
- Caution is recommended in patients with a history of DVT, pulmonary embolism, arterial thrombosis, or liver disease.

DOSE: (Refer to Product Insert)

- Dose is patient and indication specific.
- Determination of the patient's fibrinogen level before and during treatment is recommended.
- Consult with the TM Physician/Pathologist on call for bleeding patients.
- Consult with Hematologist or local hemophilia clinic for patients with congenital hypofibrinogenemia.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per nursing protocol.

Access: FIBRYGA™ can be can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies (see reconstitution instructions)

- Fibryga™ product (Vial of Fibryga™ lyophilized powder)
- 50 mL sterile water for injection (WFI - provided separately)
- Octajet® Transfer device (included with product)
- Luer Lock particle filter (included with product)
- Luer Lock syringe (large enough to contain dose)
- Alcohol swabs

Administration Supplies:

- IV administration set (no filter required)
- Microbore tubing if using syringe pump
- IV pump

Reconstitution:

- See Fibryga reconstitution instructions: https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-fibryga-recon.pdf

Administration:

- Give immediately after reconstitution.
- Do not dilute further.
- For intravenous use only.
- No other drugs or IV solutions can be co-administered in the same line while FIBRYGA™ is being infused.
- Prior to use, allow FIBRYGA™ to reach ambient room temperature (if stored refrigerator)
- Do not use solutions that are cloudy or have deposits.
- Administration rate: Maximum of 5mL/minute (Maximum pump rate = 300mL/h). Consult with physician
- **Options for Administration:**
  - **Regular IV set:** Empty IV bag and inject reconstituted FIBRYGA™ into the empty bag. Prime line with FIBRYGA™. Infuse FIBRYGA™. Flush line with 35 mL NS at the end of FIBRYGA™ infusion.
  - **Buretrol:** (In-line or 'add-a-line')
    - **Option 1:** Attach 500-mL NS bag to buretrol line. Prime tubing with 35 mL NS **(leave chamber empty)** and close clamp between NS and buretrol. Add FIBRYGA™ to chamber for infusion. Flush line at same rate with 35 mL NS at the end of FIBRYGA™ infusion to ensure entire dose has been administered.
    - **Option 2** Prime buretrol line with FIBRYGA™ (similar to tPA process). Infuse FIBRYGA™. Flush line at same rate with 35 mL NS at the end of FIBRYGA™ infusion.
  - **Direct IV:** Not to exceed 5 mL/minute.
  - **Syringe pump**: (Microbore tubing required). Not to exceed 5 mL/minute.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to:
https://www.albertahealthservices.ca/lab/Page4240.aspx

Documentation:

- The transfusion documentation must be double signed (where required) to indicate infusion.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow clinical record (electronic or paper) as required.
- Provide patient notification documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.

Side Effects		**Action**
- Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	Slow rate of infusion

Potential Allergic Reaction		**Action**
- Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY of PRODUCT:

- FIBRYGA™ product
  - Store at 2-25°C. Do not freeze.
  - Protect from exposure to light.
  - Shelf life is 36 months from the date of manufacture.
  - Stable up to 24 hours at 25°C once reconstituted
- Sterile water
  - Store at 15-30°C. Do not freeze
  - Shelf life is 48 months from date of production

COMMENTS:

Date Effective: 27 Nov 2019
Version: 1.0
Approved By: APL Transfusion Medicine Discipline Council
Document Number: TM20-01-002.002
For questions or comments regarding this document please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES:

FIBRYGA® Product Monograph (available at www.octapharma.ca)
NAC Statement on Fibrinogen Concentrate (available at www.nacblood.ca)