ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

FIBRYGA® Fibrinogen Concentrate

APPLICABILITY: This document applies to all APL, 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), FCH, FC* ***Company:*** *Octapharma* ***Class:*** *Manufactured blood product, derived from human plasma*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**IO (Intraosseous)**
Acceptable Routes*	Yes**	Yes	No	No	No	Yes

***** Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

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.
- 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 level 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 waiting for fibrinogen levels.

Don't Misuse My Blood Project

Clinical decision support tools

CONTRAINDICATIONS:

- Patients who are hypersensitive to this blood product or any ingredient in the 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: Dose is patient and indication specific, refer to the dosing chart below.

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

Pediatrics and Neonates

Clinical Indication	**Fibrinogen Level (g/L) (within last 24 hours unless no time to wait)**	**FC Dose (mg/kg)**		**Notes**
		Typical	Maximum	
Critical clinical situation	Not required	60-100 mg/kg	• None	Fibrinogen units are in grams, but pediatric dosing is mg/kg. To determine the number of 1g vials (1g=1000mg) use the following calculation: Dose (mg/kg) x Patient weight (Kg)= Total dose (mg)
Bleeding: • History of bleeding • RBC in last 24 hour • In OR within last 24h	Less than 1.5 g/L	30-60 mg/kg	• 100 mg/kg • No maximum if the fibrinogen test results indicate a correction has not occurred	
Cardiovascular surgery	Not required	Up to 100 mg/kg	• No maximum if still in OR • Once out of the OR and up to 24 hours post 100 mg/kg	
Not bleeding, acquired hypofibrinogenemia (e.g. liver dysfunction, leukemia)	Less than 1.5 g/L or no time to wait	30 mg/kg	• 60 mg/kg • No maximum if the fibrinogen test results indicate a correction has not occurred	

Adults

Clinical Indication	**Fibrinogen Level (g/L) (within last 24 hours unless no time to wait)**	**FC Dose (g)**	
		Typical	Maximum
Critical clinical situation	Not required	4g	• None
Bleeding: • History of bleeding • RBC in last 24 hour • In OR within last 24h	Less than 1.5 g/L	4g	• 8g • No maximum if the fibrinogen test results indicate a correction has not occurred
Bleeding, Obstetrical/Post-Partum hemorrhage	Less than or equal to 2.0 g/L	4g	• No maximum while still bleeding
	Greater than 2.0 g/L	2g	• No maximum while still bleeding
Cardiovascular surgery	Not required	2g	• No maximum if still in OR • Once out of the OR and up to 24 hours post, 8g
Not bleeding, acquired hypofibrinogenemia (e.g. liver dysfunction, leukemia)	Less than 1.5 g/L or no time to wait	2g	• 2g • No maximum if the fibrinogen test results indicate a correction has not occurred

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 AHS Transfusion Policy and Procedure.

Access:

- FIBRYGA® can be given via CVAD or peripheral IV line.
  - IO: optional route if no IV access is possible.
- **Note:** Air-eliminating micron filters (e.g. 0.2 and 1.2 microns) are not compatible with fibrinogen concentrate. If the patient requires a filter, a 17-micron filter or larger must be used.

Compatible IV Solutions:

- Normal saline may be used to flush the line.
- Do not mix with other products, medications, or solutions.

Reconstitution:

- See FIBRYGA Reconstitution.
- Prior to use, allow FIBRYGA® to reach ambient room temperature (if stored in refrigerator)
- After reconstitution, FIBRYGA® should be colorless and clear to slightly opalescent. Do not use if the solution is cloudy or contains particulates.
- Do not dilute further.
- FIBRYGA® should be given immediately after reconstitution.

Administration Supplies: (as needed)

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

Administration:

- Visually inspect the product prior to administration.
- Administration at room temperature is recommended.
- No other drugs or IV solutions can be co-administered in the same line while FIBRYGA® is being infused.
- **IV Administration:**

  Option 1: Administer via Direct IV:

  - Recommended rate: 20 mL/minute for uncontrolled bleeding in acquired hypofibrinogenemia
  - Recommended rate: 5 mL/minute for congenital afibrinogenemia or hypofibrinogenemia

  Option 2: Transfer to Minibag:

  - Inject reconstituted FIBRYGA® into an empty minibag.
  - Prime line with FIBRYGA®.
  - Infuse FIBRYGA®.
  - Flush line with 35 mL NS at the end of FIBRYGA® infusion.

  Option 3: Syringe pump: (Microbore tubing required).

  Option 4: Use a Buretrol: (In-line or 'add-a-line')

  - **Option A:** 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 B** 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.

- **Administration rate**:
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended maximum rate during the management of uncontrolled severe bleeding in acquired hypofibrinogenemia: 20 mL/ minute.
  - Recommended maximum rate for patients with congenital afibrinogenemia and hypofibrinogenemia: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: Transfusion Reactions | Alberta Health Services.

Documentation:

- Ensure documentation is completed as per the *AHS Transfusion of Blood Components and Products Policy and Procedure.*
- Patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification documentation as 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 - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→ **Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→ **Action** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY of PRODUCT:

- Store at 2-25°C. Do not freeze.
- Protect from exposure to light.
- Shelf life is 48 months from the date of manufacture.

Contact Information:

Approved By: APL Transfusion Medicine Discipline Council

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)

Sanders, Steven, Homer Tien, Jeannie Callum, Barto Nascimento, Henry Peng, Chris Funk, Joanne Schmid, Sandro Rizoli, Shawn Rhind, and Andrew Beckett. **"Fibrinogen Concentrate in the Special Operations Forces Environment**." *Military Medicine* 183, no. 1–2 (2018). https://doi.org/10.1093/milmed/usx057.

Schlimp, Christoph J., Cristina Solomon, Claudia Keibl, Johannes Zipperle, Sylvia Nürnberger, Wolfgang Öhlinger, Heinz Redl, and Herbert Schöchl. **"Recovery of Fibrinogen Concentrate after Intraosseous Application Is Equivalent to the Intravenous Route in a Porcine Model of Hemodilution."** *Journal of Trauma and Acute Care Surgery* 76, no. 5 (2014): 1235–42. https://doi.org/10.1097/ta.0000000000000174.