ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

RiaSTAP™ Fibrinogen Concentrate (Human)

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:*** *FCH, FC* ***Company:*** *CSL Behring* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV 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.**

**** Direct IV Administration of Blood Products may be performed by professionals per the Transfusion of Blood Components and Products Learning Module. Not to be confused with medication administration.**

DESCRIPTION:

- RiaSTAP® is a pasteurized, preservative free, lyophilized human fibrinogen concentrate.
- Contains 900 mg to 1300 mg fibrinogen/vial.
- Fibrinogen concentrate is considered interchangeable with the blood component cryoprecipitate.
- After reconstitution with 50 mL sterile water for injection, fibrinogen concentration will be approximately 20 mg/mL.
- Also contains human albumin, L-arginine hydrochloride, sodium chloride and sodium citrate.
- Latex-free.

AVAILABILITY

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

INDICATIONS FOR USE:

- Treatment of acquired and congenital fibrinogen deficiency (afibrinogenemia and hypofibrinogenemia).
- Prophylaxis in acute promyelocytic leukemia / chemotherapy (<1.5g/L).
- In a bleeding patient, when:
  - Fibrinogen level is less than 1.5 g/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 time to wait for fibrinogen level results.

CONTRAINDICATIONS:

- Patients who are hypersensitive to this product or any ingredient in the formulation or component of the container.

WARNINGS:

- Risk of thrombosis in patients with congenital deficiency exists, particularly when treated with high doses or repeated dosing.
- 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 TM Physician / Pathologist on call for bleeding patients.
- Consult with Hematologist or local bleeding disorders clinic for patients with congenital hypofibrinogenemia.
- Recommended dose for fibrinogen replacement in acquired hypofibrinogenemia:
  - Adults: 2-4 g
  - Pediatrics and neonates: 30-60 mg/kg. Consult with pediatric/neonatal coagulopathy specialist.

ADMINISTRATION:

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

Pre-Infusion:

- Ensure pertinent labs are ordered if required and time allows. (e.g. Fibrinogen, CBC)
- Perform pre-transfusion checks per AHS Transfusion Policy and Procedure.

Access:

- RiaSTAP® can be given via CVAD or peripheral venous line.
- **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.

Reconstitution:

- See RiaSTAP® Reconstitution Instructions.
- Do not dilute further.
- After reconstitution, RiaSTAP® should be colorless and clear to slightly opalescent. Do not use if the solution is cloudy or contains particulates.
- RiaSTAP® should be administered as soon as possible (within 8 hours) after reconstitution.
- Do not refrigerate after reconstitution.

Compatible IV Solutions:

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

Administration Supplies:

- IV administration set (filter not required, vented set is required if hanging the bottle)
- IV pump (if required)

Administration:

- Visually inspect the product prior to administration. Do not use products that are cloudy or contain particulates.
- Administration at room temperature is recommended.
- No other drugs or IV solutions can be co-administered in the same line while RiaSTAP® is being infused.
- **IV Administration:**

  Option 1: Infuse from the vial: (dispensing pin and filter not used)

  - Spike the vial using aseptic technique.
  - Using the plastic hanger affixed to the RiaSTAP® vial, invert the vial and hang from the IV pole.
  - Ensure the vent is open to ensure steady flow of product.
  - Infuse the prescribed amount at the appropriate rate.
  - Flush using normal saline

  Option 2: Transfer to Minibag:

  - Empty the IV bag and inject reconstituted RiaSTAP® into the empty bag.
  - Prime the line with RiaSTAP®.
  - Infuse the prescribed amount at the appropriate rate.
  - Flush using normal saline.

  Option 3: Administer via Direct IV. Flush using normal saline.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Do not exceed 20 mL/minute. *

**Maximum administration rate deviates from manufacturer recommendations. Deviation approved by APL TM Discipline Council 19 July 2021.*

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: http://www.albertahealthservices.ca/lab/page4240.aspx.

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) must 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* until expiry (up to 60 months from date of manufacture).
- Protect from light.
- Do not freeze.
- Do not use expired product.

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**Storage temperature deviates from manufacturer recommendations. Deviation approved by APL TM Discipline Council 21 June 2021*

COMMENTS:

Date Effective: 1 Sept 2021
Revision: 2.30
Approved By: APL Transfusion Medicine Discipline Council
Document Number: TM40-01.02.020
For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

RiaSTAP™ Manufacturer Product Insert (available at www.cslbehring.ca)
NAC Statement on Fibrinogen Concentrate (available at www.nacblood.ca)