### Description of Product:
- 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 (included with product), fibrinogen concentration in each vial will be approximately 20 mg/mL.
- Also contains human albumin, L-arginine hydrochloride, sodium chloride and sodium citrate.
- Latex-free

### Availability
- Supplied by CBS.
- 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 (allergic) to this drug or any ingredient in formulation (see Description of Product).

### 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 hemophilia clinic for patients with congenital hypofibrinogenemia.
ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product 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: RiaSTAP™ can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:
- RiaSTAP product (Vial of RiaSTAP™ lyophilized powder and 50 mL sterile water for injection)
- Alcohol swabs
- Sterile plastic Luer lock syringe
- Blunt transfer needle

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

Reconstitution:
- See reconstitution instructions http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-riastap-recon-inst.pdf
- NOTE: If product and diluent are not at room temperature prior to reconstitution, time to dissolve will be extended if product/diluent is cold.

Administration:
- Give immediately after reconstitution (within 8 hours). Administration at room temperature is recommended. DO NOT refrigerate after reconstitution.
- Do not dilute further.
- No other drugs or IV solutions can be co-administered in the same line while RiaSTAP™ is being infused.
- Administration rate: Maximum of 5 mL/minute (Maximum pump rate = 300 mL/h). Consult with physician.
  - Options for Administration:
    - Regular IV set: Empty IV bag and inject reconstituted RiaSTAP™ into the empty bag. Prime line with RiaSTAP™. Infuse RiaSTAP™. Flush line with 35 mL NS at the end of RiaSTAP™ 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 RiaSTAP™ to chamber for infusion. Flush line at same rate with 35 mL NS at the end of RiaSTAP™ infusion to ensure entire dose has been administered.
      - Option 2: Prime buretrol line with RiaSTAP™ (similar to tPA process). Infuse RiaSTAP™. Flush line at same rate with 35 mL NS at the end of RiaSTAP™ infusion.
    - Direct IV: Not to exceed 5 mL/minute.
    - Syringe pump: (Microbore tubing required). Not to exceed 5 mL/minute (Pump rate: maximum 300 mL/h).
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/4240.asp

Documentation:
- The transfusion documentation should 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 chart or 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
- 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:
- Stored at 2-25°C*. **Do not freeze.**
- Protect from light during storage.
- Shelf life is 60 months from date of manufacture.
- Do not use expired product.

*Storage temperature deviates from manufacturer recommendations. Deviation approved by APL TM Discipline Council 17 May 2019

COMMENTS:
Date Effective: 23 July 2019
Version: 1.3
Approved By: Alberta Public Laboratories Transfusion Medicine Discipline Council
Document Number: PTMGNR00025

For questions or comments regarding this document please contact: Transfusion.SafetyTeam@albertahealthservices.ca

REFERENCES:
RiaSTAP™ Product Monograph (available at www.cslbehring.ca)
NAC Statement on Fibrinogen Concentrate (available at www.nacblood.ca)