RiaStap

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Fibrinogen Concentrate	None

PREPARATION and ADMINISTRATION

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

Reconstitution

Diluent: Sterile Water for injection

See pages 3-4 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 at a maximum infusion rate of 5 mL per minute.	**IV Bag (large volume pump)**	**IV Bag (large volume pump)**
	Inject solution into an empty 50-100 mL IV bag to infuse Administer at a maximum infusion rate of 5 mL per minute.	Not applicable
	Syringe (syringe pump)	**Syringe (syringe pump)**
	Administer at a maximum infusion rate of 5 mL per minute.	Not applicable

Requirements and Monitoring

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.

INDICATIONS

Indicated for:

The treatment of congenital fibrinogen deficiency (congenital afibrinogenemia and hypofibrinogenemia).

ADVERSE EFFECTS

The most common adverse reactions that have been reported in clinical are allergic reactions and generalized reactions such as chills, fever, nausea, and vomiting.

The most serious adverse reactions observed in subjects treated with RiaSTAP during clinical studies are allergic-anaphylactic reactions and thromboembolic episodes including myocardial infarction, pulmonary embolism, deep vein thrombosis, and arterial thrombosis.

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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. 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

If the patient's fibrinogen level is not known, the recommended dose is an IV administration of 70 mg/kg body weight.
Minor events (e.g. epistaxis, intramuscular bleeding, or menorrhagia): the target level (1 g/L) should be maintained for at least 3 days.

Major events (e.g. head trauma, or intracranial hemorrhage): the target level (1.5 g/L) should be maintained for 7 days.

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

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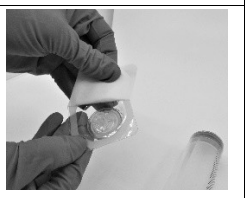
RECONSTITUTION

1. Warm both the powder (RiaStap) and 50 mL solvent (Water for Injection) in unopened bottles up to room temperature. Put on clean gloves before proceeding.	
2. Remove the cap from the powder 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 to dry.	
3. Using a 60 mL syringe with a red blunt needle attached, inject 50 mL of air into the diluent (sterile water) vial, then draw up 50 mL of diluent. Next, inject the diluent into the product vial.	
4. Gently swirl the product vial to ensure the product is fully dissolved (generally 5 to 10 minutes). Do not shake the vial which causes formation of foam.	
5. Open the plastic blister containing the mini-spike dispensing pin provided with RiaSTAP (Image 1).	
6. Take the provided dispensing pin and insert it into the stopper of the vial with the reconstituted product (Image 2).	
7. After the dispensing pin is inserted, remove the blue cap. After the blue cap is removed, do not touch the exposed surface.	
8. Open the blister with the “syringe filter” provided with RiaSTAP (Image 3).	
9. Screw the syringe onto the filter (Image 4).	

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10. Screw the syringe with the mounted filter onto the dispensing pin (Image 5).	
11. Draw the reconstituted product into the syringe (Image 6).	
12. When completed, remove the filter, dispensing pin and empty vial from the syringe, dispose of properly, and proceed with administration.	

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- RiaStap product monograph. Found at https://www.cslbehring.ca/products/product-list