
 <p>DIAGNOSTIC SERVICES MANITOBA</p> <p>SERVICES DIAGNOSTIC MANITOBA</p>	Fibrinogen Concentrate		Document # 160-65-21
			Version # 01
	Approved by:  Dr. Charles Musuka	Effective Date: 27-OCT-2016	Source Document: Blood Product Administration Guidelines from Manufactures Monographs

Other Names	<ul style="list-style-type: none"> RiaSTAP, FCH
Description	<ul style="list-style-type: none"> RiaSTAP pasteurized, preservative free, lyophilized fibrinogen concentrate derived from human plasma. Contains 900 mg to 1300 mg fibrinogen/vial After reconstitution with 50 mL sterile water for injection (may not be included), 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
Special Approvals/Authorizations	<ul style="list-style-type: none"> An independent 2-person check is required for all doses, as per Canadian standards. Nurses from the Manitoba Bleeding Disorder Program are exempt from the independent 2-person check. Approval for the product must be on the written order of the attending hematologist or designate. The physician's order must include the number of grams (mgs) required. The hematologist or their designate must approve dose changes. Contact the Bleeding Disorder Nurse Clinicians at (204) 787-2071, pager 3346; or the Adult/Pediatric Hematologist on call through paging (204) 787-2071. Patients accustomed to self-administration may continue do so on the written order of a hematologist or designate.
Classification	<ul style="list-style-type: none"> Coagulation factor, manufactured blood product (human) – purified concentration of fibrinogen
Indications	<ul style="list-style-type: none"> Treatment of congenital fibrinogen deficiency (afibrinogenemia and hypofibrinogenemia)
Contraindications	<ul style="list-style-type: none"> Patients who are hypersensitive (allergic) to this drugs or any ingredient in formulation (see the above description of product) Warnings: <ul style="list-style-type: none"> 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 deep vein thrombosis, pulmonary embolism, arterial thrombosis or liver disease.
Supplied	<ul style="list-style-type: none"> 1 gram vial containing 900 mg to 1300 mg of fibrinogen RiaSTAP consists of two boxes: The product box contains one single-use RiaSTAP vial (with hanger attached) and the diluent box contains one single-use sterile water for injection vial (50 mL).
Dosage	<ul style="list-style-type: none"> Doses determined by body weight and clinical need. Dose when fibrinogen level is not known: 70 mg/kg
Reconstitution/Stability	<p>Reconstitution</p> <ul style="list-style-type: none"> Upon receiving product from blood bank, warm vial in hands to bring to room temperature, reconstitute contents of each 1-gram vial with 50 mL sterile water for injection (may not be provided). Gently roll to mix. Do not shake. Remove the cap from the product vial to expose the central portion of the rubber stopper. Clean the surface of the rubber stopper with an antiseptic solution and allow it to dry. Using an appropriate transfer device or syringe, transfer 50 mL of sterile water for injection into the product vial. Gently swirl the product vial to ensure the product is fully dissolved (generally 10 minutes to 15 minutes). Do not shake the vial that causes formation of foam. Reconstituted product should be administered immediately by a separate injection/infusion line. <p>Stability</p> <ul style="list-style-type: none"> Store at temperatures of 2°C to 25°C. Do not freeze. Protect from light. Stable for the period indicated by the expiration date on the carton and vial label Keep in its original carton until ready to use.

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	<ul style="list-style-type: none">Stability of final admixture: Stable for 8 hours after reconstitution when stored at 20°C to 25°C.
Compatibilities/ Incompatibilities	<ul style="list-style-type: none">Reconstitute with sterile water. DO NOT dilute with IV fluids or other drugs in syringe or bag prior to administration.No other drugs / solutions (including normal saline) can be co-administered in the same line
Administration, Identification	Refer to Manitoba Best Practice Guidelines <ul style="list-style-type: none">section 2.2 Standards- Identification and Administration
Administration, Method	<ul style="list-style-type: none">Intermittent:<ul style="list-style-type: none">Administer 0.5 mL/minute to 1 mL/minute via Viaflex© bag or syringe pump into port closest to vein.Slowly increase rate by 1 mL every 15 minutes to a maximum rate of 5 mL/minute only if patient is tolerating infusion.Flush with 3 mL to 5 mL normal saline.Central:<ul style="list-style-type: none">Administer 0.5 mL/minute to 1 mL/minute via Viaflex© bag or syringe pump.Flush with 10 mL to 20 mL normal saline.Maximum Rate: 5 mL/minute (Please also refer to patient specific protocol). Patient specific protocols are developed by Bleeding Disorder Team and are available for all patients requiring fibrinogen replacement. Please refer to protocol for infusion instructions.Maximum concentration: As reconstituted (per manufacturer's instructions)
Adverse Events	Refer to Manitoba Best Practice Guidelines section 2.7 for transfusion reactions.
Resources:	For further information refer to: <ul style="list-style-type: none">RiaSTAP monograph available at: http://labelling.cslbehring.ca/PM/CA/RiaSTAP/EN/RiaSTAP-Product-Monograph.pdfNAC prothrombin complex recommendations: http://www.nacblood.ca/resources/guidelines/fibrinogen.html