FIBRINOGEN CONCENTRATE & PROTHROMBIN COMPLEX CONCENTRATE: TRANSFUSIONISTS CONCENTRATE ON …

September 27, 2023

FIBRINOGEN CONCENTRATE (FC) SUMMARY

1. What is FC?

Brand	Fibryga®	RiaSTAP®
Composition per 1 g vial	Human Fibrinogen 1000 mg	Human Fibrinogen 900-1300 mg
	Nonmedicinal ingredients: Glycine, sodium chloride, L-Arginine hydrochloride, sodium citrate dihydrate.	Nonmedicinal ingredients: Human albumin, sodium chloride, L-arginine hydrochloride, sodium citrate, sodium hydroxide (for pH adjustment).

NOTE (per National Advisory Committee on Blood & Blood Products [NAC])
Cryoprecipitate is manufactured (by Canadian Blood Services [CBS]) from slowly thawed frozen plasma and is indicated for replacement of fibrinogen.
In terms of clinical effectiveness, there is no evidence of superiority of one fibrinogen replacement source.
FC is pathogen inactivated and thus its safety profile (transmissible disease risk) is favoured.
Also, FC provides a precise fibrinogen dose and simpler preparation (thawing is not required; bedside reconstitution is an option).

2. FC Indications/Transfusion Guidelines

Brand	Fibryga®	RiaSTAP®
Per product monograph	➢ "treatment of acute bleeding episodes & perioperative prophylaxis in adult & pediatric patients with congenital afibrinogenemia & hypofibrinogenemia" ➢ a therapy for management of uncontrolled severe bleeding in patients with acquired fibrinogen deficiency during surgical interventions	➢ "treatment of congenital fibrinogen deficiency which comprises congenital afibrinogenemia and hypofibrinogenemia"
National Advisory Committee on Blood & Blood Products [NAC]	➢ As per product monographs ➢ "The use … in acquired hypofibrinogenemia is supported by studies, including a high-quality randomized trial in bleeding patients undergoing cardiovascular surgery" ➢ including bleeding obstetrical patients "among others" ➢ "both fibrinogen concentrates appear to have similar efficacy in improving clot firmness in a dilutional hypofibrinogenemia model in vitro"	
Bloody Easy 5.1 [BE 5.1] (p.127)	➢ As per product monographs ➢ "Major or massive hemorrhage from surgery or trauma when fibrinogen <1.5 g/L." ➢ "Acute phase of acute promyelocytic leukemia with fibrinogen <1.5 g/L." ➢ "Hemorrhage after cardiac surgery or peripartum with fibrinogen <2.0 g/L." ➢ "Intracranial hemorrhage secondary to treatment with Tissue Plasminogen Activator with fibrinogen <2.0 g/L."	

(Lab test: Clauss fibrinogen assay; Normal fibrinogen 1.5 to 4 g/L)

3. FC Administration

Required: Informed consent; product checks – patient identification, lot number, expiry & visual inspection.

Brand	Fibryga®	RiaSTAP®
Dose	- Acquired fibrinogen deficiency: adults 4 g (4 of 1 g vials), final volume 200 mL per 4 g dose. - Congenital afibrinogenemia & hypofibrinogenemia: dose calculation per product monograph	
TML Storage	Room temperature, up to 36 months	Refrigerator, up to 60 months
Reconstitution	- Packaged with solvent Sterile Water for Injection vial (50 mL), Octajet transfer device, & particle filter. - Use Aseptic technique. - Gently swirl the vial to ensure fully dissolved (from 5 up to 30 minutes). Do not shake. - Do not use solutions that are cloudy or have deposits. - Reconstituted, fibrinogen concentration is 20 mg/mL. - Label product appropriately.	- Packaged with diluent Sterile Water for Injection vial (50 mL), mini-spike® dispensing pin, & syringe filter. - Bring diluent & product vials to room temp. - Use Aseptic technique - Gently swirl the vial to ensure fully dissolved (about 5 to 10 minutes). Do not shake. - Should be clear & colourless, otherwise do not use. - Reconstituted, fibrinogen concentration is 20 mg/mL. - Label product appropriately.
Expiry post reconstitution	Should be used immediately, otherwise responsibility of the user. (Stability has been demonstrated for up to 24 hours at +25°C).	Stable for 8 hours after reconstitution when stored at room temperature & should be administered within this time.

Brand	Fibryga®	RiaSTAP®
Tubing	Standard IV tubing (filtered as part of reconstitution procedure)	
IV Fluid	Flush infusion site with 0.9% sodium chloride prior to & following administration.	
Infusion Rate	For patients with acquired fibrinogen deficiency (i.e., bleeding patient), maximum rate of 20 mL per minute (1,200 mL/hour).	Slow intravenous infusion, not exceeding 5 mL per minute (300 mL/hour).
Patient Monitoring	- Assess for signs & symptoms of allergic transfusion reaction (hives, rash, facial or airway edema, difficulty breathing, tachycardia, hypotension). - Use of FC is associated with risk of thrombosis. Monitor for signs & symptoms: leg or arm swelling, feeling warm to touch, red discolouration, tenderness or cramping; shortness of breath, chest/back pain with breathing).	
Lab test monitoring	Following infusion, repeat fibrinogen immediately/within 60 minutes Expected fibrinogen increment is approximately 0.5-1.0 g/L.	

References:

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