University of Colorado Hemophilia & Thrombosis Center Pharmacy: ADDITIONAL INFUSED FACTOR PRODUCTS

Hemophilia and Thrombosis Center
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

	C-PROTEIN CONCENTRATE	FIBRINOGEN CONCENTRATE	FX	FXIII	
	CEPROTIN	RIASTAP®	COAGADEX®	CORIFACT®	TRETTEN®
MANUFACTURER	SHIRE (formerly Baxalta)	CSL BEHRING	BIO PRODUCTS LABORATORY LIMITED	CSL BEHRING	NOVO NORDISK
U.S. LICENSURE DATE	2007	2009	2015	2013	2013
CLASSIFICATION	PROTEIN C	FIBRINOGEN CONCENTRATE	PLASMA DERIVED FACTOR X	FACTOR XIII (Plasma) Pooled	FACTOR XIII (Recombinant)
SOURCE MATERIAL	Pooled Human Plasma	Pooled Human Plasma	Pooled Human Plasma	FACTOR XIII (Plasma)	Recombinant Human factor XIII-A_2 manufactured as an intracellular, soluble protein in yeast (Saccharomyces cerevisiae) production strain.
PROTEIN PURIFICATION METHOD	Immunoaffinity chromatography	Glycine precipitation	Anion exchange chromatography Salt precipitation	Ion exchange chromatography, 20nm filtration Precipitation/adsorption; Ion exchange chromatography; Heat treatment; Virus filtration	Hydrophobic interaction and ion exchange chromatography
VIRAL INACTIVATION ATTENUATION METHODPROCESS	Detergent treatment; heat inactivation; Immunoaffinity chromatography	Cryoprecipitation; absorption/precipitation; heat treatment ; glycine precipitation	Solvent/Detergent Nanofiltration Dry heat treatment	Precipitation/adsorption; Ion exchange chromatography; Heat treatment; Virus filtration	N/A
INACTIVE INGREDIENTS	Albumin, heparin, mouse protein, sodium chloride, trisodium citrate dihydrate	Albumin, l-arginine hydrochloride, NaCl, sodium citrate, NaOH, HCl	Chloride, phosphate, citrate, sucrose and sodium -Contains ≤ 1 IU/ml of FII and X in the final reconstituted product.	Human albumin, NaCl, glucose, sodium hydroxide	NaCl, sucrose, polysorbate-20, L-Histidine
MEAN HALF-LIFE	Non-compartmental approach: Mean 9.88 hours (95% CI for median 7.1-11.6; Min 4.9, Max 14.7)	78.7 ± 18.13 hours (may be shorter in pediatric patients)	30.3 hrs.	Pediatrics ≤ 16 yo: 5.7 ± 1.00 days 6.6 ± 2.29 days	5.1 days
BOX CONTENTS	Diluent: Sterile Water for Injection 5 mL (500 IU), 10 mL (1000 IU) Sterile Water, transfer needle, filter needle.	One vial of RiaSTAP. Does not include 50 mL diluent or transfer device.	Diluent: 2.5 mL (250 IU), 5ml (500 IU) Sterile Water for Injection, Mix2Vial™ transfer device.	Diluent: 20 mL Sterile Water for Injection, a Mix2Vial filter transfer set one alcohol swab.Pediatrics ≤ 16 yo: 5.7 ± 1.00 days 6.6 ± 2.29 days	Diluent: 3.2 mL Sterile Water for Injection, vial adapter
AVAILABLE ASSAYS	500 IU, 1000 IU	900 mg to 1300 mg	250 IU, 500 IU	1000-1600 IU per vial	2500 IU per vial (2000-3125 IU per vial)

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INFUSION RATE	Not to exceed 0.2 mL/kg/minute Infuse within 3 hours of reconstitution.	Not to exceed 5 mL/minute Infuse within 8 hours of reconstitution.	10 ml/min not to exceed 20 ml/min Use within one hour of reconstitution.	Do not exceed an infusion rate greater than 4 mL/minute Use within 4 hours of reconstitution.	Do not exceed 1-2 mL/minute Use within 3 hours of reconstitution. If the reconstituted product is not used immediately, store the solution refrigerated or at room temperature not to exceed 25°C (77°F) for up to 3 hours following reconstitution.
STORAGE REQUIREMENTS	▫Refrigerate at 36°F–46°F (2°C–8°C) until expiration date. ▫Do not freeze. ▫Keep the vial in the original carton and protect from light.	▫Store room temperature ≤ 77°F (25°C) until expiration date. ▫Do not freeze. ▫Keep the vial in the original carton and protect from light.	Store in refrigerator or at room temperature < 30°C (36°F -86°F) ▫Do not freeze. ▫Store in the original package and protect from light.	▫Refrigerate 2-8 °C (36-46°F) Do not freeze and protect from light. May be stored at room temperature ≤ 25 °C (77 °F) for up to 6 months. ▫Do not freeze. ▫Do not return the product to the refrigerator after it is stored at room temperature. ▫Store vial in original box and protect from light.	▫Refrigerate 2-8 °C (36-46°F) to expiration date. ▫Do not freeze ▫Store vial in original box and protect from light and protect from light.
DOSING GUIDELINES	**Acute Episode/Short term prophylaxis:** Initial dose: 100-120 IU/kg Subsequent 3 doses: 60-80 IU/kg every 6 hours Maintenance dose: 45-60 IU/kg every 6 or 12 hours **Long-term Prophylaxis:** 45-60 IU/kg every 12 hours. NOTE: Dose, administration frequency and duration of treatment is dependent the severity of the Protein C deficiency. **The dose regimen should be adjusted according to the pharmacokinetic profile for each patient.** An initial dose of 100-120 IU/kg for determination of recovery and half-life is	RiaSTAP dose when baseline fibrinogen level is known: Dose (mg/kg body weight) = [Target level (mg/dL) - measured level (mg/dL)] 1.7 (mg/dL per mg/kg body weight) RiaSTAP dose when baseline fibrinogen level is not known: 70 mg/kg (body weight) NOTE: Monitoring of patient's fibrinogen level is recommended during treatment with RiaSTAP. A target fibgrinogen level of 100 mg/dL should be maintained until hemostasis is obtained.	**Dose (IU) =Body Weight (kg) x Desired Factor X Rise (IU/dL) x 0.5** **Bleeding episodes:** 25 IU/ kg/dose, repeated at intervals of 24 hours until the bleed stops. **For perioperative management:** **Pre-Surgery:** Increase plasma Factor X levels to 70-90 IU/dL. **Post-surgery:** Maintain plasma Factor X levels at a minimum of 50 IU/dL until the patient is no longer at risk of bleeding due to surgery. •The dosage and duration of treatment is dependent on the severity of the Factor X deficiency, on the location and extent of the bleeding and on the patient's clinical condition.	**Prophylaxis**: 40 IU/kg every 28 days **SEE PI FOR PERI-OPERATIVE AND SURICAL DOSING GUIDELINES**	**Prophylaxis:** 35 IU/kg once a month

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DOSING GUIDELINES (Cont'd)	recommended. After resolution of acute episode, continue patient on dose to maintain a trough protein C activity level about 25%	Dose should be individually calculated for each patient based on the target plasma fibrinogen level based on the type of bleeding, actual measured plasma fibrinogen level and body weight.			
FDA APPROVED INDICATION	Pediatric and adult patients with severe congenital Protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans.	Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogemia. NOT indicated for dysfibrinogenemia.	For use in patients >12 years old with hereditary Factor X deficiency for: ☑Treatment and control of bleeding episodes ☑Perioperative management	Prevention and control of bleeding in adults and children: ☑Routine prophylaxis ☑Perioperative management	Prevention of bleeding in adults with factor XIII **A-subunit** deficiency: ☑**R**outine prophylaxis
COMMENTS	-Contains trace amounts of heparin that may lead to heparin-induced thrombocytopenia. -Patient on a low sodium diet should be informed that the quantity of sodium in the maximum daily dose of Ceprotin exceeds 200 mg.	Reconstitute each vial with 50 mL of Sterile Water for Injection, which is NOT included with the product.	Each vial labeled in number Factor X in international units (IU) Note: Perioperative management of bleeding in major surgery in patients with moderate and severe hereditary Factor X deficiency has not been studied.	Do not exceed an infusion rate greater than 4 mL/minute Contains factor XIII subunit A and B	No human or animal derived products used in the manufacturing process **Contains only factor XIII subunit-A** **Do not administer TRETTEN®with recombinant factor FVIIa**

NOTE: Recombinant technology may be the ONLY product of choice for patients of Jehovah's Witnesses faith.

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MEDICATION CHART DISCLAIMER

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