Additional Factor Products

Product Specifics	Coagadex BPL	Corifact CSL Behring	Tretten Novo Nordisk	OBIZUR Shire	NovoSeven® RT Novo Nordisk	Feiba NF Shire
Indications	Indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for: On-demand treatment and control of bleeding episodes AND Perioperative management of bleeding in patients with mild hereditary Factor X deficiency. Perioperative management of bleeding in major surgery in patients with moderate and severe hereditary Factor X deficiency has not been studied.	Indicated for routine prophylactic treatment and peri-operative management of surgical bleeding in adult and pediatric patients with congenital Factor XIII deficiency	Indicated for routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency. TRETTEN® is not for use in patients with congenital factor XIII B-subunit deficiency	Indicated for the treatment of bleeding episodes in adults with acquired hemophilia A	• Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors • Congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. • Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia.	FEIBA is an Anti-Inhibitor Coagulant Complex indicated for use in hemophilia A and B patients with inhibitors for: • Control and prevention of bleeding episodes • Perioperative management • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. FEIBA is not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.
Contraindications	COAGADEX® is contraindicated in patients who have had life-threatening hypersensitivity reactions to COAGADEX or any of the components	Patients with known anaphylactic or severe systemic reactions to human plasma-derived products	Hypersensitivity to the active substance or to any of the excipients.	Do not use in patients who have had life-threatening hypersensitivity reactions to OBIZUR or its components, including hamster protein.	None	• History of known anaphylactic or severe hypersensitivity reactions to FEIBA or any if its components, including factors of the kinin generating system. • Disseminated intravascular coagulation (DIC). • Acute thrombosis or embolism (including myocardial infarction).
Viral Safety Processes	1) Solvent/detergent treatment ; 2) A 15-nm filtration 3) Terminal dry-heat treatment	Using serological assays for hepatitis B surface antigen and antibodies to HIV-1/2 and HCV. The plasma is tested with Nucleic Acid Testing (NAT) for HCV, HIV-1, HAV and HBV and found to be non-reactive (negative), and the plasma is also tested by NAT for Human Parvovirus B19. Only plasma that passed virus screening is used for production. Purified by the following four steps: • Precipitation/adsorption • Ion exchange chromatography • Heat-treatment (+60°C for 10 hours in an aqueous solution) • Virus filtration over two 20 nm filters in series	Purification by several chromatography steps, including hydrophobic interaction and ion exchange chromatography.	The production process includes two dedicated viral clearance steps - a solvent/detergent treatment step for viral inactivation and a nanofiltration step through a series of two 15-nm filters for removal of viruses	Chromatographic purification process to remove exogenous viruses	Vapor Heat Treatment and 35 nm Nanofiltration
Product Half Life	30.3 hours	6.6 days ± 2.29	Mean (SD); 7.1 (1.9) days	10 hours mean; range 2.6 - 28.6 hours	Hemophilia A or B t½ = 2.6-3.1 hours Congenital Factor VII deficiency t½ = 2.82 - 3.11 hours	N/A; Dosing intervals: 6 - 12 hours by type of hemorrhage
Product Recovery Percentage	2.08	N/A	N/A	A positive response was observed in 95% (19/20) of subjects evaluated at 8 hours and 100% (18/18) at 16 hours.	Hemophilia A or B patients, the incremental recovery was 45.63%. In Congenital Factor VII deficiency, the incremental recovery was (18.9% and 22.2% with 15 and 30 mcg per kg doses.	N/A
Manufacturing Method	Manufactured from plasma	Manufactured from cryo-depleted plasma into an ethanol precipitate, which is then purified by the following four steps: • Precipitation/adsorption • Ion exchange chromatography • Heat-treatment (+60°C for 10 hours in an aqueous solution) • Virus filtration over two 20 nm filters in series	Recombinant	OBIZUR is expressed in a genetically engineered baby hamster kidney (BHK) cell line which secretes rpFVIII into the cell culture medium. No additives of human or animal origin are used in the formulation of OBIZUR.	Recombinant	Plasma
Storage Requirements	Store COAGADEX in its original package to protect it from light. Store the COAGADEX package in a refrigerator or at room temperature (36°F to 86°F). Do not freeze.	Refrigeration at 2-8°C (36-46°F) or room temperature not to exceed 25°C (77°F) for 6 months	• Store refrigerated at 2°C – 8°C (36°F – 46°F) prior to reconstitution. TRETTEN ® is stable until the expiration date on the carton and vial label. Do not freeze. Store protected from light. • Use reconstituted TRETTEN ® within 3 hours. • 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	• Store OBIZUR at refrigeration temperature of 2° to 8°C [36° to 46°F]. Do not freeze. • Store vials in the original package to protect from light. • Do not use beyond the expiration date printed on the carton or vial. • Use OBIZUR within 3 hours after reconstitution. • Discard any unused reconstituted product if not used within 3 hours after reconstitution. • Do not use OBIZUR if the reconstituted solution is cloudy or has particulate matter	Prior to reconstitution, keep refrigerated or store between 2–25°C/36–77°F. Do not freeze. Store protected from light. Do not use past the expiration date. After reconstitution, NovoSeven® RT may be stored either at room temperature or refrigerated for up to 3 hours. Do not freeze reconstituted NovoSeven® RT or store it in syringes.	• Store at room temperature, not to exceed 25°C (77°F). • Store in the original package in order to protect from light. • Do not freeze.
Shelf Life from Date of Manufacture	36 months	Stable for 24 months, up to the expiration date on the carton and vial labels. Within the expiration date, Corifact may be stored at room temperature not to exceed 25°C (77°F) for up to 6 months.	24 months	24 months	36 months	24 months
How Supplied / Diluent Volume	250 IU: 2.5 mL or 500 IU: 5 mL	20 mL vial of Sterile Water for Injection	The actual amount of TRETTEN® in international units (IU) is stated on each carton and vial. TRETTEN® and the sterile water vials provided in the package are not made with natural rubber latex. After reconstitution with 3.2 mL of sterile water for injection, each vial contains 667-1042 IU/mL of recombinant coagulation factor XIII A-subunit.	1 mL	In a NovoSeven® RT package containing 1 vial of NovoSeven® RT powder and 1 pre-filled histidine diluent syringe with vial adapter for needleless reconstitution, the specified volume of diluent corresponding to the amount of NovoSeven® RT is as follows: 1 mg (1,000 micrograms) vial + 1 mL Histidine diluent in pre-filled syringe, 2 mg (2,000 micrograms) vial + 2 mL Histidine diluent in pre-filled syringe, 5 mg (5,000 micrograms) vial + 5 mL Histidine diluent in pre-filled syringe, 8 mg (8,000 micrograms) vial + 8 mL Histidine diluent in pre-filled syringe. After reconstitution with the specified volume of diluent, each vial contains approximately 1mg/mL NovoSeven® RT (1,000 micrograms/mL).	500 U, 1,000 U: 20 mL 2,500 U: 20mL or 50 mL