

	Factor X	Factor XIII	
Product Specifics	<b>Coagadex®</b> BPL	<b>Corifact®</b> CSL Behring	<b>Tretten®</b> Novo Nordisk
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 adults and pediatric patients with congenital factor XIII deficiency for: 1) routine prophylactic treatment 2) peri-operative management of surgical bleeding	Routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency.  TRETEN® is not for use in patients with congenital factor XIII B-subunit deficiency
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.
Viral Safety Processes	Solvent/detergent treatment; 15-nm filtration; Terminal dry-heat treatment	<ul style="list-style-type: none"> <li>• Precipitation/adsorption</li> <li>• Ion exchange chromatography</li> <li>• Heat-treatment (+60°C for 10 hours in an aqueous solution)</li> <li>• Virus filtration over two 20 nm filters in series</li> </ul>	Purification by several chromatography steps, including hydrophobic interaction and ion exchange chromatography.
Product Half Life	30.3 hours	6.6 days ± 2.29	7.1 days + 1.9
Product Recovery Percentage	2.08	N/A	N/A
Manufacturing Method	Manufactured from plasma, obtained from healthy US donors, who have passed viral screening tests. Three processing steps specifically designed to remove or inactivate viruses are: Solvent/detergent treatment targeted to inactivate enveloped viruses; A 15-nm filtration step designed to remove small viruses including non-enveloped viruses; and Terminal dry-heat treatment at 80°C for 72 hours in the final container to inactivate enveloped and non-enveloped viruses.	Pooled human plasma	Recombinant Coagulation Factor XIII A-Subunit manufactured as an intracellular, soluble protein in yeast ( <i>Saccharomyces cerevisiae</i> ) production strain containing the episomal expression vector, pD16. It is subsequently isolated by homogenization of cells and purified by several chromatography steps, including hydrophobic interaction and ion exchange chromatography.
Storage Requirements	<ul style="list-style-type: none"> <li>• Store COAGADEX in its original package to protect it from light.</li> <li>• Store the COAGADEX package in a refrigerator or at room temperature (36°F to 86°F). Do not freeze. Use reconstituted COAGADEX within one hour of reconstitution.</li> </ul>	<ul style="list-style-type: none"> <li>• Refrigerate Corifact at 2-8°C (36-46°F). Keep in original carton to protect from light. Do not freeze.</li> <li>• Corifact is stable for 36 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.</li> <li>• Do not return the product to the refrigerator after it is stored at room temperature. Clearly mark the beginning date of room temperature storage on the carton label.</li> <li>• Do not use beyond the expiration date on the carton and vial labels, or end of the period for room temperature storage, whichever comes first.</li> <li>• This product does not contain a preservative and must be used within 4 hours after reconstitution.</li> <li>• Do not refrigerate or freeze the reconstituted solution.</li> </ul>	<ul style="list-style-type: none"> <li>• Store refrigerated at 2°C – 8°C (36°F – 46°F) prior to reconstitution. TRETEN® is stable until the expiration date on the carton and vial label. Do not freeze. Store protected from light.</li> <li>• Use reconstituted TRETEN® within 3 hours.</li> <li>• 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</li> </ul>
Shelf Life from Date of Manufacture	36 months	Corifact is stable for 36 months, up to the expiration date on the carton and vial labels.	Prior to reconstitution and under refrigeration, Tretten® is stable until the expiration date on the carton and vial label.
How Supplied / Diluent Volume	250 IU (2.5 mL) or 500 IU (5 mL)	1000-1600 IU: 20 mL vial of Sterile Water for Injection	The actual amount of TRETEN® in international units (IU) is stated on each carton and vial. TRETEN® 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.