

Product Specifics	Helixate® FS	Kogenate® FS available with BIO-SET Needleless Reconstitution Device	Xyntha™	ReFacto®	Recombine	Advate
Indications	Hemophilia A with deficiency of clotting Factor VIII	Hemophilia A with deficiency of clotting Factor VIII	XYNTHA Antihemophilic Factor (Recombinant), Plasma/Albumin-Free is indicated for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia). XYNTHA does not contain von Willebrand factor, and therefore is not indicated in von Willebrand's disease.	ReFacto® Antihemophilic Factor (Recombinant) is indicated for the control and prevention of hemorrhagic episodes and for surgical prophylaxis in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia). ReFacto is indicated for short-term routine prophylaxis to reduce the frequency of spontaneous bleeding episodes. The effect of regular routine prophylaxis on long-term morbidity and mortality is unknown.	Prevention and control of bleeding episodes and perioperative management in patients with hemophilia A; may be of therapeutic value in patients with FVIII inhibitors not exceeding 10 BU	Prevention and control of bleeding episodes in patients with hemophilia A; can be of therapeutic value in patients with FVIII inhibitors not exceeding 10 BU
Contraindications	Known hypersensitivity to mouse or hamster protein. Known intolerance or allergic reactions to constituents of the preparation.	Known hypersensitivity to mouse or hamster protein; known intolerance or allergic reactions to constituents of the preparation is a contraindication to the use of Kogenate FS	None Known	Known hypersensitivity to mouse of hamster proteins may be a contraindication	Known hypersensitivity to mouse, hamster, or bovine protein.	Known hypersensitivity to mouse or hamster proteins. Known life threatening immediate hypersensitivity reactions, including anaphylaxis, to the product. Known intolerance or allergic reaction to any of the constituents of the formulation.
Nutrient in Cell Culture	The cell culture medium contains Human Plasma Protein Solution (HPPS) and recombinant insulin, but does not contain any proteins derived from animal sources.	human plasma protein solution	The cell line is grown in a chemically defined cell culture medium that contains recombinant insulin, but does not contain any materials derived from human or animal sources.	The CHO cell line secretes B-domain deleted recombinant factor VIII into a defined cell culture medium that contains human serum albumin and recombinant insulin, but does not contain any proteins derived from animal sources.	Bovine serum albumin	Plant - Soy
Stabilizer in Final Formulation	Sucrose (0.9-1.3%), Glycine (21-25 mg/mL), and Histidine (18-23mM)	Sucrose 28 mg - 250, 500, 1000 iu vial sizes 56 mg - 2000 iu vial size	Sucrose	Sucrose	Human Albumin, calcium, polyethylene glycol, sodium, histidine, polysorbate-80	Mannitol, trehalose, sodium, histidine, Tris, calcium, polysorbate 80, glutathione
Viral Removal Process	Ion Exchange Chromatography and Monoclonal Antibody Immuno-Affinity Chromatography	Ion exchange chromatography and monoclonal antibody Immuno-Affinity chromatography	The Antihemophilic Factor (Recombinant), Plasma/Albumin-Free in XYNTHA is purified by a process that uses a series of chromatography steps, one of which is based on affinity chromatography using a patented synthetic peptide affinity ligand. The process also includes a virus-retaining nanofiltration step.	The protein is purified by a chromatography purification process that yields a high-purity, active product.	Immuno-Affinity Chromatography and Ion Exchange Chromatography	Immuno-Affinity Chromatography and Ion Exchange Chromatography
Viral Inactivation Process	Solvent/Detergent	Solvent/Detergent Treatment	Solvent/Detergent	Solvent/Detergent	N/A	Solvent/Detergent
Product Half Life	Approximately 13 hours	Approximately 13 hours	11.2 ± 5.0 hours	14.8 ± 5.6 hours	14.6 ± 4.9 hours	11.98 ± 4.28 hours
Product Recovery Percentage	2.1 ± 0.3% /iu/kg	2.1 ± 0.3% /iu/kg	2.15 ± 0.44	Mean incremental recovery: 2.4 + 0.4iu/dL per iu/kg	2.4	2.41
Storage Requirements	Store in refrigerator at 2°-8°C (36°-46°F) for period indicated by the expiration date on the label. Within this period, Helixate FS may also be stored at room temperature, not to exceed 25°C (77°F) for up to 3 months, such as in home treatment situations. Do not freeze. Protect from extreme exposure to light and store the lyophilized powder in the carton prior to use.	27 months under refrigeration plus three months room temperature (30 months total)	Refrigeration at a temperature of 2°-8°C (36°-46°F) XYNTHA may also be stored at room temperature not to exceed 25°C (77°F) for up to 3 months, until the expiration date. At the end of the 3-month period, the product should not be put back into the refrigerator, but should be used immediately or discarded. The diluent syringe may be stored at 2°-25°C (36°-77°F) Freezing should be avoided to prevent damage to the pre-filled diluent syringe. During storage, avoid prolonged exposure of XYNTHA vial to light. Do not use XYNTHA after the expiration date on the label.	Refrigeration at a temperature of 2°-8°C (36°-46°F). ReFacto® may also be stored at room temperature not to exceed 25°C (77°F) for up to 3 months, until the expiration date. Freezing should be avoided to prevent damage to the diluent syringe. Avoid prolonged exposure of vial to light. Do not use ReFacto® after the expiration date on the label.	Refrigeration 2°-8°C (36°-46°F) or room temperature, not to exceed 30°C or 86°F until expiration date noted on package	2°-8°C (36°-46°F). May be stored at room temperature, up to 30°C (86°F) for up to 6 months or until expiration date, whichever ever comes first
Shelf Life from Date of Manufacture	24 months under refrigeration	24 months under refrigeration	24 months	24 months	36 months	24 months
Diluent Volume	250 iu - 2.5 mL, 500 iu - 2.5 mL 1000 iu - 2.5 mL, 2000 iu - 5 mL	250 iu - 2.5 mL, 500 iu - 2.5 mL 1000 iu - 2.5 mL, 2000 iu - 5 mL	4 mL for all vial sizes	4 mL for all vial sizes	10 mL	5 mL

IMPORTANT NOTICE - The information provided herein is a summary of available information only. This summary is to be used as a general educational tool and is not intended for use as a guideline for clinical evaluations. Such evaluations (including but not limited to initial and/or subsequent dosing, conversions from specific product brands, etc.) should utilize a thorough review of appropriate clinical data. For a copy of a product insert or to request any additional information at our disposal, please contact us at 1-800-948-9834. The possibility of error (typographical or otherwise) exists in this summary. No liability is assumed by the distributor for improper use of this literature. Updated September 2008. ©2008. BDI Pharma, Inc. All rights reserved.