

Recombinant Factor VIII



800.948.9834 ■ www.bdipharma.com

PRODUCT SPECIFICS	Kogenate® FS (available with BIO-SET Needleless Reconstitution Device)	XYNTHA™	Helixate® FS	Recombinate	Advate
INDICATIONS	Control and prevention of bleeding episodes in adults and children (0-16 years) with Hemophilia A; Peri-operative management in adults and children with Hemophilia A; Routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with Hemophilia A with no pre-existing joint damage.	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 patients with von Willebrand's disease. XYNTHA™ Antihemophilic Factor (Recombinant), Plasma/Albumin-Free is indicated for surgical prophylaxis in patients with Hemophilia A.	For control and prevention of bleeding episodes in adults and children with Hemophilia A; peri-operative management in adults and children and routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with Hemophilia A with no pre-existing joint damage	In Hemophilia A for the prevention and control of hemorrhagic episodes. Also indicated in the perioperative management of patients with Hemophilia A.	1. Control and prevention of bleeding episodes in adults and children (0-16 years) with Hemophilia A. 2. Perioperative management in adults and children (0-16 years) with Hemophilia A.
CONTRAINDICATIONS	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins	Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster proteins.	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins	In patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including bovine, mouse, or hamster proteins.	Known anaphylaxis to mouse or hamster protein or other constituents of the product.
NUTRIENT IN CELL CULTURE	The cell culture medium contains human plasma protein solution and recombinant insulin, but does not contain any proteins derived from animal sources.	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 cell culture medium contains Human Plasma Protein Solution (HPPS) and recombinant insulin, but does not contain any proteins derived from animal sources.	Bovine serum albumin and aprotinin	plant-soy
STABILIZER IN FINAL FORMULATION	Sucrose: 0.9-1.3% (250 IU, 500 IU, 1000 IU); 0.9-1.2% (2000 IU, 3000 IU) Glycine: 21-25 mg/mL (250 IU, 500 IU, 1000 IU); 20-24 mg/mL (2000 IU, 3000 IU) Histidine: 18-23 mmol/L (250 IU, 500 IU, 1000 IU); 17-22 mmol/L (2000 IU, 3000 IU)	Sucrose	Sucrose (0.9-1.3%), Glycine (21-25 mg/mL), and Histidine (18-23mM) (250 IU, 500IU, 1000 IU)	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 immunoaffinity 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.	Ion Exchange Chromatography and Monoclonal Antibody Immunoaffinity Chromatography	immunoaffinity chromatography	immunoaffinity chromatography
VIRAL INACTIVATION PROCESS	Solvent/Detergent Treatment	Solvent/Detergent	Solvent/Detergent	N/A	Solvent/Detergent
PRODUCT HALF LIFE	13.74 ± 1.82 hours	11.2 + 5.0 hours (initial visit); 11.8 + 6.2 (6 month follow-up visit)	13.7 ± 1.82 hours	14.6 ± 4.9 hours	Adults >16 years: 12.03 ± 4.15, infants 8.86 ± 1.78, 2 to 5 year olds: 10.27 ± 1.94, 5 to <12 year olds 10.89 ± 1.60, 12 to <16 year olds 11.70 ± 3.72
PRODUCT RECOVERY PERCENTAGE	2.20 ± 0.34	103 + 21% (initial visit); 116% + 40 (6 month follow-up visit)	2.1 ± 0.3 %/IU/kg and 1.25-2.76 %/IU/kg in children	Calculated ratio of actual to expected recovery; 121.2 ± 48.9%. Actual baseline recovery observed was 123.9 ± 47.7 IU/dl.	Recovery IU/dL/IU/kg in vivo adults: 2.57 ± 0.53, IU/dL/IU/kg infants: 1.96 ± 0.21, 2 to <5 years 2.05 ± 0.62, 5 to <12 years 2.21 ± 0.44, 12 to <16 years 2.26 ± 0.42
STORAGE REQUIREMENTS	Product as Packaged for Sale: Store Kogenate® FS at +2°C to +8°C (36°F to 46°F) for up to 30 months from the date of manufacture. Within this period, Kogenate® FS may be stored for a period of up to 12 months at temperatures up to +25°C or 77°F, such as in home treatment situations. The starting date of room temperature storage should be clearly recorded on the unopened product carton. Once stored at room temperature, the product must not be returned to the refrigerator. The shelf-life then expires after the storage at room temperature, or the expiration date on the product vial, whichever is earlier. Do not use Kogenate® FS after the expiration date indicated on the vial. Do not freeze. Protect from extreme exposure to light and store the lyophilized powder in the carton prior to use. Product After Reconstitution: Administer Kogenate® FS within 3 hours after reconstitution. It is recommended to use the administration set provided.	Product as Packaged for Sale: (1) Store XYNTHA™ under refrigeration at a temperature of 2° to 8°C (36° to 46°F) for up to 36 months from the date of manufacture until the expiration date stated on the label. Within the expiration date, XYNTHA™ may also be stored at room temperature not to exceed 25°C (77°F) for up to 3 months. After room temperature storage, XYNTHA™ can be returned to the refrigerator until the expiration date. Do not store XYNTHA™ at room temperature and return it to the refrigerator more than once. (2) The starting date at room temperature storage should be clearly recorded in the space provided on the outer carton. At the end of the 3-month period, the product must be used immediately, discarded, or returned to refrigerated storage. The diluent syringe may be stored at 2° to 25°C (36° to 77°F). (3) Do not use XYNTHA™ after the expiration date. (4) Do not freeze to prevent damage to the prefilled diluent syringe. (5) During storage, avoid prolonged exposure of XYNTHA™ vial to light. Product After Reconstitution: Administer XYNTHA™ within 3 hours after reconstitution. The reconstituted solution may be stored at room temperature prior to administration.	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 12 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.	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 comes first
SHELF LIFE FROM DATE OF MANUFACTURE	30 months	36 months	24 months under refrigeration	36 months	24 months
DILUENT VOLUME	250iu - 2.5ml, 500iu - 2.5ml, 1000iu - 2.5ml, 2000iu - 5ml, 3000iu - 5ml	250 IU - 4 mL, 500 IU - 4 mL, 1000 IU - 4 mL, 2000 IU - 4 mL, 3000 IU - 4 mL	250 IU - 2.5 mL, 500 IU - 2.5 mL, 1000 IU - 2.5 mL, 2000 IU - 5 mL, 3000 IU - 5mL	5 mL, 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. ©2011. BDI Pharma, Inc. All rights reserved.