Specialty Therapeutic Care™

An AcariaHealth Solution

Factor Product Guide for Hemophilia Patients

We've gathered information from numerous manufacturers to provide you with a useful guide to understanding some of the common Factor VIII, Von Willebrand's and Factor IX products available today.

For a full product list, or if you have any questions after reviewing this information, please consult your doctor, the manufacturers listed or contact our specialists at Specialty Therapeutic Care.

FACTOR VIII

FACTOR VIII PRODUCTS ARE LISTED FROM SHORTEST TO LONGEST HALF-LIFE

Product Name	XYNTHA (Recombinant F VIII)	ADVATE (Recombinant Factor VIII)	KOGENATE FS (Recombinant Factor VIII)	KOVALTRY (Recombinant Factor VIII)
Manufacturer	PFIZER U.S.	TAKEDA	BAYER PHARMACEUTICALS	BAYER PHARMACEUTICALS
Website	www.xyntha.com	www.advate.com	www.kogenatefs.com	www.kovaltry-us.com
Indications	Prevention and control of bleeding episodes in adults and children with hemophilia A; Surgical prophylaxis in adults and children with hemophilia A; Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A.	For use in adults and children with hemophilia A to prevent and control bleeding episodes, as surgical prophylaxis, and as routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes.	For use in adults and children with hemophilia A to prevent and control bleeding episodes, as surgical prophylaxis, and as routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes; For use in children without preexisting joint damage as routine prophylactic treatment to reduce the frequency of bleeding episodes and reduce the risk of joint damage.	For use in adults and children with hemophilia A to prevent and control bleeding episodes, as surgical prophylaxis, and as routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes.
Diluent Volume/Assay Size	Vials: 250 IU, 500 IU, 1000 IU, 2000 IU Solofuse: 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU. All products require 4mL of diluent.	250 IU, 500 IU, 1000 IU, and 1500 IU = 2 mL of diluent; 2000 IU, 3000, 4000 IU = 5mL of diluent	250IU, 500IU, 1000IU = 2.5mL of diluent; 2000IU, 3000IU = 5mL of diluent	250IU, 500IU, 1000IU = 2.5mL of diluent; 2000IU and 3000IU = 5 mL of diluent
Product Half Life	Children and Adolescents: 6.9 to 8.3 hours; Adults 11 to 17 hours	Children <12 years: 8.7 to 11.2 hours; Adolescents and Adults: 12 hours	Children: 10.7 (7.8–15.3) hours Adolecents and Adults: 13.74 ± 1.82 hours	Children <12 years: ~12 hours; Children > 12 years, Adolescents, and Adults: ~14 hours
Storage Requirements	Vials: Store at room temperature (not to exceed 77°F) for up to 3 months. After room temperature storage product may be returned to the refrigerator until the expiration date; however, do not store at room temperature and return to refrigerator temperature more than once. Avoid prolonged exposure to light during storage. Use within 3 hours of reconstitution. Solofuse: Store at room temperature (not to exceed 77°F) for up to 3 months. Do not return to refrigerator. After 3 months at room temperature, product must be used immediately or discarded. Use product within 3 hours of reconstitution.	May be stored at room temperature (up to 86°F) for up to 6 months. Use within 3 hours of reconstitution.	May be stored up to 12 months at room temperature, but not to be returned to refrigerator after storing at room temperature. After reconstitution, store Kogenate FS solution at room temperature and administer within 3 hours.	May store at room temperature up to 77°F for up to 12 months. Administer reconstituted KOVALTRY as soon as possible. If not, store at room temperature for no longer than 3 hours.
Viral Inactivation Treatment	The purification process 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 solvent-detergent viral inactivation step and a virus-retaining nanofiltration step.	The cell culture and purification processes used in the manufacture of ADVATE employ no additives of human or animal origin. The production process includes a dedicated, viral inactivation solvent-detergent treatment step.	The purification process includes a solvent/detergent virus inactivation step in addition to the use of the purification methods of ion exchange chromatography, monoclonal antibody immunoaffinity chromatography, along with other chromatographic steps designed to purify recombinant factor VIII and remove contaminating substances.	Detergent virus inactivation step, and a 20nm filtration step for removal of viruses and potential protein aggregates.
Plasma Source	Recombinant factor VIII	Recombinant factor VIII	Recombinant factor VIII	Recombinant factor VIII
Presence of von Willebrand Factor	N/A	N/A	N/A	N/A
Nutrient in Cell Culture	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 and purification processes used in the manufacture of ADVATE employ no additives of human or animal origin.	Cell culture medium contains human plasma protein solution and recombinant insulin, but does not contain any proteins derived from animal sources. No human or animal proteins, such as albumin, are added during the purification and formulation processes.	Kovaltry is produced by genetically engineered Baby Hamster Kidney (BHK) cells into which the human Factor VIII gene has been introduced. Human- and animal-derived raw materials are not added to the cell culture, purification or formulation processes.
Stabilizer in Final Formulation	Sucrose, L-histidine, and polysorbate 80	Mannitol, trehalose, histidine, Tris, polysorbate 80, and glutathione	Sucrose, glycine and histidine, polysorbate 80	Glycine, sucrose, histidine, and polysorbate 80

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FACTOR VIII (CONT'D)

FACTOR VIII PRODUCTS ARE LISTED FROM SHORTEST TO LONGEST HALF-LIFE

Product Name	AFSTYLA (Recombinant FVIII, Single Chain)	ADYNOVATE (Recombinant Factor VIII - PEGylated)	NUWIQ (Recombinant Factor VIII)	ELOCTATE (Recombinant Factor VIII, long-acting)
Manufacturer	CSL BEHRING	TAKEDA	OCTAPHARMA USA	SANOFI-GENZYME
Website	www.afstyla.com	www.adynovate.com	www.nuwiqusa.com	www.eloctate.com
Indications	Prevention and control of bleeding episodes in adults and children with hemophilia A; Surgical prophylaxis in adults and children with hemophilia A; Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A.	For use in adults and children with hemophilia A for on demand treament and control of bleeding episodes, surgical prophylaxis, and routine prophylaxis to reduce the frequency of bleeding episodes.	For use in adults and children with hemophilia A for on demand treament and control of bleeding episodes, surgical prophylaxis, and routine prophylaxis to reduce the frequency of bleeding episodes.	For use in adults and chilren with hemophilia A for on demand treatment and control of bleeding episodes, for surgical prophylaxis, and for routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes.
Diluent Volume/Assay Size	250 IU, 500 IU, 1000 IU = 2.5mL of diluent 1500 IU, 2000 IU, 2500 IU, 3000 IU= 5mL of diluent	250 IU, 500 IU, 750IU, 1000 IU, 1500 IU = 2ml of diluent; 2000 IU, 3000 IL = 5mL of diluent	250 IU, 500 IU, 1000 IU, 2000 IU, 2500 IU, 3000 IU, 4000 IU = 2.5mL of diluent	250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU, 4000IU, 5000IU, 6000IU = 3 mL of diluent
Product Half Life	Children < 12 years: 10.2 - 10.4 hours; Chidren > 12 years: 14.3 hours; Adults: 14.2 hours	Children <6 years of age: 11.8 ± 2.43 hours; Children 6 to <12 years of age: 12.4 ± 1.67 hours; Children and Adolescents 12 to <18 years of age: 13.43 ± 4.05 hours; Adults ≥18 years of age: 14.69 ± 3.79 hours.	Children < 12 years: 11.9 to 13.1 hours; Adolescents and Adults: 17.1 hours	Children <12 years: 12.7 to 14.9 hours; Children ≥12 years, Adolescents, and Adults: 16.4 to 19.7 hours
Storage Requirements	When stored at room temperature (not to exceed 77°F), use product within 3 months. Do not return to refrigerator. Store in original package to protect from light. Use within 4 hours of reconstitution.	Product may be stored at room temperature not to exceed 86°F for a period of up to 3 months (not to exceed the expiration date). Following reconstitution, use immediately or within 3 hours.	When stored at room temperature (not to exceed 77°F), use product within 3 months. Do not return to refrigerator. Store in original package to protect from light. Use within 3 hours of reconstitution.	May store at room temperature (not to exceed 86°F) for up to 6 months, but do not return the product to the refrigerator. Use within 3 hours of reconstitution; do not refrigerate after reconstitution. Protect from direct sunlight.
Viral Inactivation Treatment	AFSTYLA is purified by a controlled multi-step process including two virus reduction steps complementing each other in their mode of action. No human or animal derived proteins are used in the purification or formulation processes.	Dedicated viral inactivation solvent-detergent treatment step.	The active substance is concentrated and purified by a series of chromatography steps, which also includes two dedicated viral clearance steps: solvent/detergent (S/D) treatment for virus inactivation and 20 nm nanofiltration for removal of viruses.	The production process also incorporates two dedicated viral clearance steps — a detergent treatment step for inactivation and a 15nm filtration step for removal of viruses.
Plasma Source	Recombinant Factor VIII	Recombinant factor VIII, PEGylated	Recombinant factor VIII	Recombinant factor VIII
Presence of von Willebrand Factor	N/A	N/A	N/A	N/A
Nutrient in Cell Culture	AFSTYLA is a single-chain recombinant Factor VIII produced in chinese hamster ovary (CHO) cells. No human or animal derived proteins are used in the purification or formulation processes.	The cell culture, pegylation, purification process and formulation used in the manufacture of ADYNOVATE do not use additives of human or animal origins.	BDD-rFVIII is produced by recombinant DNA technology in genetically modified human embryonic kidney (HEK) 293F cells with no animal or human derived materials added during the manufacturing process or to the final product.	BDD-rFVIIIFc is produced by recombinant DNA technology from a human embryonic kidney (HEK) cell line, which has been extensively characterized. The HEK cell line expresses DBB- rFVIIIFc into a defined, cell culture medium that does not contain any proteins derived from animal or human sources.
Stabilizer in Final Formulation	L-histidine, sucrose, and polysorbate 80	Tris (hydroxymethyl) aminomethane, mannitol, trehalose, glutathione, histidine, and polysorbate 80	Sucrose, L-arginine hydrochloride, poloxamer, and sodium citarte dihydrate	Sucrose, L-histidine, and polysorbate 20

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FACTOR VIII (CONT'D)

FACTOR VIII PRODUCTS ARE LISTED FROM SHORTEST TO LONGEST HALF-LIFE

Product Name	JIVI (Recombinant FVIII (PEGylate-aucl))	ESPEROCT (Recombinant FVIII, Glycopegylated-exei)	HEMLIBRA (Humanized, Monoclonal Modified Immunoglobulin G4 Bispecific Antibody) Binding Factor IXa and Factor X
Manufacturer	BAYER PHARMACEUTICALS	NOVO NORDISK	GENENTECH
Website	www.jivi-us.com	www.esperoct.com	www.hemlibra.com
Indications	For use in previously treated adults and adolescents (12 years of age and older) with hemophilia A for on demand treament and control of bleeding episodes, surgical prophylaxis, and routine prophylaxis to reduce the frequency of bleeding episodes. Jivi is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions.	For use in adults and children with hemophilia A for on demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged newborn and older with hemophilia A with or without factor VIII inhibitors.
Diluent Volume/Assay Size	500 IU, 1000 IU, 2000 IU, 3000 IU = 2.5 mL of diluent	500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU = 4mL of diluent	30mg/1 mL; 60mg/0.4mL; 105mg/0.7mL; 150mg/1 mL
Product Half Life	Children ≥12 years of age, Adolescents, and Adults: 17.4 ± 3.8 to 21.4 ± 13.1 hours	Children <6 years of age: 14.7 hours; Children 6 to <12 years of age: 13.8 hours; Children and Adolescents 12 to <18 years of age: 17.4 hours; Adults ≥18 years of age: 21.7 hours.	26.9 ± 9.1 days
Storage Requirements	May be stored up to 77°F for up to 6 months. After storage at room temperature, do not return to refrigerator. Following reconstitution, use immediately or may store at room temperature for up to 3 hours before administration.	May store vials at up to 86°F for up to 12 months or up to 104°F for no longer than 3 months. After storage at room temperature, do not return to refrigerator. Following reconstitution, use immediately or store at room temperature (<86°F) for not more than 4 hours or refrigerated (36°F to 46°F) for not more than 24 hours before administration.	May store unopened vials at <86°F for up to 7 days. Once removed from the vial, discard if not used immediately. Discard unused solution.
Viral Inactivation Treatment	A series of chromatography and filtration steps occur including 20nm viral filtration prior to conjugation to the 60 kDa maleimide PEG moiety. The cell culture, PEGylation, purification process and formulation used in the manufacture of Jivi do not use any additives of human or animal origins.	The purification process includes two viral clearance steps, namely detergent (Triton X-100) treatment for inactivation of enveloped viruses, and 20-nm filtration for removal of enveloped and non-enveloped viruses. No additives of human or animal origin are used during the manufacturing process.	N/A
Plasma Source	Recombinant factor VIII, PEGylated	Recombinant factor VIII, PEGylated	N/A
Presence of von Willebrand Factor	N/A	N/A	N/A
Nutrient in Cell Culture	The cell culture, PEGylation, purification process and formulation used in the manufacture of Jivi do not use any additives of human or animal origins.	FVIII protein in ESPEROCT® is produced in Chinese Hamster Ovary (CHO) cells using recombinant DNA technology. No additives of human or animal origin are used during the manufacturing process and formulation of ESPEROCT.	Produced in genetically engineered mammalian (Chinese hamster ovary) cells.
Stabilizer in Final Formulation	Glycine, sucrose, histidine, and polysorbate 80	L-histidine, sucrose, polysorbate 80, and L-methionine	L-arginine, L-histidine, poloxamer, and L-aspartic acid

VON WILLEBRAND'S

Product Name	STIMATE (Nasal Spray - Desmopressin)	WILATE (Human Complex VWF + Factor VIII (Ratio of 1:1))	HUMATE-P (FVIII with VFW Complex (Human)(Ratio 1:2.4)
Manufacturer	CSL BEHRING	OCTAPHARMA USA	CSL BEHRING
Website	www.cslbehring.com	www.wilateusa.com	www.humate-p.com
Indications	Stimate is indicated for patients with hemophilia A with Factor VIII coagulant activity levels greater than 5% to maintain hemostasis during surgial procedures and postoperatively. Stimate will also stop bleeding in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding. Stimate is also indicated for patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII coagulant activity levels greater than 5%.	Treatment and prevention of bleeding in adults and pediatric patients ≥12 years of age with hemophilia A; On demand treatment and control of bleeding episodes, and perioperative management of bleeding in adult and pediatric patients with von Willebrand disease.	Treatment and prevention of bleeding in adults with hemophilia A; Treatment of spontaneous or trauma-induced bleeding, as well as prevention of excessive bleeding during and after surgery in adult and pediatric patients with severe von Willebrand disease, including mild or moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate. Limitations of use: Safety and efficacy of prophylactic dosing to prevent spontaneous bleeding have not been conducted in patients with von Willebrand disease.
Diluent Volume/Assay Size	2.5 mL bottle with spray pump capable of delivering 25 sprays of 150 mcg	500 units VFW + 500 units FVIII = 5mL of diluent 1000 units VFW + 1000 units FVIII = 10mL of diluent	600IU VWF + 250 IU FVIII= 5mL of diluent; 1200 IU VWF + 500 IU FVIII = 10mL of diluent; 2400 IU VWF 1000 IU FVIII = 15mL of diluent
Product Half Life	3.3 to 3.5 hours	Factor VIII - pediatric: 9 to 15 hours; adults: 6 to 15 hours VFW:Rco - 6 to 49 hours	Patients with Hemophilia A - 8 to 17 hours; Patients with von Willebrand disease - 3 to 34 hours
Storage Requirements	Store at room temperature not to exceed 25°C (77°F) for the period indicated by the expiration date on the label. Discard six months after being opened. Store bottle in upright position.	Intact vials may be stored at room temperature (not to exceed 77°F) for up to 6 months. Once stored at room temperature, do not return to the refrigerator. Following reconstitution, use solution immediately.	When stored at temperatures up to 25°C (77°F), Humate-P is stable for 36 months up to the printed expiration date. Humate-P does not contain a preservative and should be used within 3 hours after reconstitution.
Viral Inactivation Treatment	N/A	Solvent/detergent treatment, terminal dry-heat treatment at 100°C for 120 minutes	The virus inactivation/removal capacity consists of four steps: Cryoprecipitation, Al(OH)3 adsorption, glycine precipitation, and NaCl precipitation, studied in combination, Heat treatment at 60°C for 10 hours in aqueous solution, and Lyophilization.
Plasma Source	Synthetic analogue of the natural pituitary hormone 8-arginine vasopressin (ADH), an antidiuretic hormone affecting renal water conservation.	Pooled human plasma	Pooled human plasma
Presence of von Willebrand Factor	N/A	Yes; Ratio 1:1	Yes; the average ratio of VWF:RCo to FVIII is 2.4:1.
Nutrient in Cell Culture	N/A	N/A	N/A
Stabilizer in Final Formulation	Citric acid monohydrate and disodium phosphate dihydrate	Glycine, sucrose, sodium citrate, and polysorbate 80	Albumin human, glycine, and sodium citrate

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VON WILLEBRAND'S

Product Name	VONVENDI (Recombinant von Willebrand Factor)	ALPHANATE (Factor Complex that contains Factor VIII + VWF (Ratio 1:1.38 ± 0.3))
Manufacturer	TAKEDA	GRIFOLS
Website	www.vonvendi.com	www.alphanate.com
Indications	On-demand treatment and control of bleeding episodes and perioperative management of bleeding in adults with von Willebrand disease.	Treatment and prevention of bleeding in adult and pediatric patients with factor VIII deficiency due to hemophilia A; Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease when desmopressin is either ineffective or contraindicated. Limitations of use: Not indicated for patients with severe von Willebrand disease (type 3) undergoing major surgery.
Diluent Volume/Assay Size	650 units (450-850 range) = 5mL of diluent; 1300 units (900-1700 range) = 10mL of diluent	250IU & 500IU = 5mL of diluent; 1000IU, 1500IU, 2000IU = 10mL of diluent
Product Half Life	19.1 to 22.6 hours	17.9 ± 9.6 hours in hemophilia A patients 7.67 ± 3.3 for VWF in VWD patients 21.58 ± 7.79 for FVIII in VWD patients
Storage Requirements	Store at refrigerated temperature 2°C to 8°C (36°F to 46°F) or room temperature not to exceed 30°C (86°F). Store in the original box and protect from extreme exposure to light. Use reconstituted product immediately or within 3 hours after reconstitution.	Stable for three years, up to the expiration date printed on its label, provided that the storage temperature does not exceed 25 °C (77 °F). Use the prepared drug as soon as possible within 3 hours after reconstitution.
Viral Inactivation Treatment	VONVENDI is a purified rVWF expressed in Chinese Hamster Ovary (CHO) cells. VONVENDI is produced and formulated without the addition of any exogenous raw materials of human or animal origin in the cell culture, purification, or formulation of the final product.	Solvent/detergent treatment and heat treatment at 80° for 72 hours
Plasma Source	Recombinant von Willebrand factor	Pooled human plasma
Presence of von Willebrand Factor	Yes	Yes
Nutrient in Cell Culture	VONVENDI is produced and formulated without the addition of any exogenous raw materials of human or animal origin in the cell culture, purification, or formulation of the final product.	N/A
Stabilizer in Final Formulation	Tri-sodium citrate dihydrate, glycine, mannitol, trehalose-dihydrate, and polysorbate 80	Albumin human, arginine, and histidine

FACTOR IX

FACTOR IX PRODUCTS ARE LISTED FROM SHORTEST TO LONGEST HALF-LIFE

Product Name	BENEFIX (Recombinant Factor IX)	IXINITY (Recombinant Factor IX)	RIXUBIS (Recombinant Factor IX)
Manufacturer	PFIZER	MEDEXUS PHARMACEUTICALS	TAKEDA
Website	www.benefix.com	www.ixinity.com	www.rixubis.com
Indications	On demand treatment and control of bleeding episodes in patients with hemophilia B; perioperative management in patients with hemophilia B; routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia B.	On demand treatment and control of bleeding episodes in patients with hemophilia B; perioperative management in patients with hemophilia B; routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia B.	On demand treatment and control of bleeding episodes in patients with hemophilia B; perioperative management in patients with hemophilia B; routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia B.
Diluent Volume/Assay Size	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU = 5mL of diluent	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU = 5mL of diluent	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU = 5mL of diluent
Product Half Life	2 to 11: 14.4 to 18.6 hours; Patients 12 years and older: 18.7 to 27.5 hours	Patients 12 years of age and older: 13 to 43 hours (mean 24 hours)	Patients 6 to 11 years: 23.7 to 32 hours (mean 25-27 hours). Patients 12 years of age and older 15.8 to 52 hours (mean 26.7 hours)
Storage Requirements	Can be stored at room temperature up to 86°F. Once reconstituted, product should be used within 3 hours. Do not use product after the date of expiration.	Only the 250 IU strength should be stored refrigerated. All other strengths store at room temperature up to 77°F. Infuse reconstituted solution immediately or within 3 hours of storage at room temperature. Do not refrigerate after reconstitution.	When stored at room temperature, the product should be used within 36 months. Do not exceed 86 °F.
Viral Inactivation Treatment	Not derived from human blood. Its manufacturing and purification process include no added human or animal proteins. It is produced by a genetically engineered Chinese hamster ovary (CHO) cell line that is extensively characterized. The process also includes a membrane nanofiltration step.	Three validated viral inactivation/removal steps—solvent/detergent, chromatograpy, and nanofiltration—plus a validated step to reduce the presence of CHO proteins.	The process includes validated virus inactivation/ removal steps, namely solvent/detergent treatment and nanofiltration.
Plasma Source	Recombinant factor IX	Recombinant factor IX	Purified protein produced by recombinant DNA technology
Presence of von Willebrand Factor	N/A	N/A	N/A
Nutrient in Cell Culture	It is produced by a genetically engineered Chinese hamster ovary (CHO) cell line that is extensively characterized. No additives of animal or human origin are used during the cell culture, purification, and formulation processes of BeneFIX.	Coagulation factor IX is secreted by using an engineered cell line derived from Chinese hamster ovary (CHO) cells. No human or animal proteins are added during any stage of manufacturing or formulation.	No human or animal proteins are added during any stage of manufacturing or formulation of RIXUBIS. Non-blood based nutrients added to feed cells.
Stabilizer in Final Formulation	L-histidine, sucrose, glycine, and polysorbate 80	Histidine, mannitol, trehalose dihydrate, and polysorbate 80	L-histidine, mannitol, sucrose, and polysorbate 80

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FACTOR IX (CONT'D)

FACTOR IX PRODUCTS ARE LISTED FROM SHORTEST TO LONGEST HALF-LIFE

Product Name	ALPROLIX (Recombinant Factor IX (Fc Fusion Protein))	IDELVION (Recombinant Factor IX, Albumin Fusion Protein)
Manufacturer	SANOFI-GENZYME	CSL BEHRING
Website	www.alprolix.com	www.idelvion.com
Indications	On demand treatment and control of bleeding episodes in patients with hemophilia B; perioperative management in patients with hemophilia B; routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia B.	Prevention and on demand control of bleeding episodes in adults and children with Hemophilia B; perioperative management of bleeding in adults and children with Hemophilia B; routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with Hemophilia B.
Diluent Volume/Assay Size	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU, and 4000 IU = 5mL of diluent	250IU, 500IU, 1000IU = 2.5mL of diluent; 2000IU, 3500IU = 5mL of diluent
Product Half Life	2 to 11 years: 66 to 72 hours; 12 to 17 years: 84 hours; Adults: 87 hours	Patients less than 18 years: 87 to 93 hours; Adults: 104 to 118 hours
Storage Requirements	When stored at room temperature, do not exceed 86°F. On the carton, record the date when the product was removed from refrigeration. Use the product within a 6 month period. Do not place the product back into refrigeration after warming to room temperature. Once reconstituted, may be stored at room temperature for no longer than 3 hours.	May be stored in the refrigerator or at room temperature from 36°F to 77°F. Do not freeze. Store in package to protect from light. Reconstituted solution should be used immediately or within 4 hours of preparation.
Viral Inactivation Treatment	Not derived from human blood and contains no preservatives. The recombinant Factor IX Fc fusion protein is expressed in a human embryonic kidney (HEK) cell line, which produces rFIXFc into a defined cell culture medium that does not contain proteins derived from animal or human sources. The purification process for rFIXFc does not include use of a monoclonal antibody reagent. To enhance viral safety, the purification process incorporates a filtration step and a detergent treatment step that have been validated for viral clearance.	Contains trace amounts of Chinese hamster ovary (CHO) proteins. There are three validated virus clearance steps, including virus inactivation by solvent/detergent treatment and virus removal by filtration.
Plasma Source	Recombinant factor IX	Purified protein produced by recombinant DNA technology
Presence of von Willebrand Factor	N/A	N/A
Nutrient in Cell Culture	ALPROLIX is not derived from human blood and contains no preservatives. The recombinant Factor IX Fc fusion protein is expressed in a human embryonic kidney (HEK) cell line, which produces rFIXFc into a defined cell culture medium that does not contain proteins derived from animal or human sources.	IDELVION is a glycoprotein consisting of 1018 amino acids secreted by a genetically engineered Chinese hamster ovary (CHO) cell line. The CHO cell line secretes rIX-FP into a defined cell culture medium and the rIX-FP protein is purified by a process that does not require the use of a monoclonal antibody reagent. Mammalian cell cultivation in vitro requires a complex combination of nutrients, considering glucose and glutamine as main carbon, energy and nitrogen.
Stabilizer in Final Formulation	Sucrose, mannitol, L-histidine and polysorbate 20	Sodium citrate, polysorbate 80, mannitol and sucrose

Bleeding Disorders Resources

National and World Organizations

National Hemophilia Foundation (NHF)*

Hope For Hemophilia*

Hemophilia Federation of America (HFA)*

LA Kelley Communications

World Federation of Hemophilia

*Directory for local bleeding disorder chapters available on website

Patient Assistance

Healthcare.gov

Patient Services Inc. (PSI)

Patient Access Network (PAN) Foundation

Specialty Therapeutic Care is a helpful resource for patient services including reimbursement and payment assistance options.
Call 866.506.2626 to find out how we can help.

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