

# Comparison Chart of Anti-Hemophilic Factor VIII

Product Specifics	Helixate® FS	Kogenate® FS	Recombinate	Advate	Humate-P®	Monarc-M	Hemofil M	Monoclate-P®	Koate®-DVI	Alphanate®
Indications	Hemophilia A	Hemophilia A with deficiency of clotting Factor VIII	Prevention and control of bleeding episodes and perioperative management in patients with hemophilia A; of therapeutic value in patients with FVIII inhibitors not exceeding 10 BU	Prevention and control of bleeding episodes in patients with hemophilia A; of therapeutic value in patients with FVIII inhibitors not exceeding 10 BU	Hemophilia A and von-Willebrand Disease	Hemophilia A, Acquired Factor VIII inhibitors not exceeding 10 BU	Prevention and control of bleeding episodes in patients with hemophilia A; of therapeutic value in patients with FVIII inhibitors not exceeding 10 BU	Hemophilia A	Hemophilia A (deficiency of clotting Factor VIII)	Hemophilia A or acquired Factor VIII deficiency
Contraindications	Hypersensitivity to mouse or hamster protein	Know hypersensitivity to mouse or hamster protein	Know 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	None known	Know hypersensitivity to mouse protein	Know hypersensitivity to mouse protein	Hypersensitivity to mouse protein	None known	None known
Viral Removal Process	Monoclonal Antibody Immuno-Affinity Chromatography	N/A	Immuno-Affinity Chromatography and Ion Exchange Chromatography	Immuno-Affinity Chromatography and Ion Exchange Chromatography	Absorption and Precipitation Process	Monoclonal Antibody Immuno-Affinity Chromatography	Monoclonal Antibody Immuno-Affinity Chromatography	Monoclonal Antibody Immuno-Affinity Chromatography	N/A	Affinity Chromatography heparin-coupled, cross linked agarose which has an affinity to the heparin binding domain of vWF/F VIII: C Complex, 3.5% PEG Precipitation
Viral Inactivation Process	Solvent/Detergent	Solvent/Detergent Treatment	N/A	Solvent/Detergent	Pasteurization	Solvent/Detergent	Solvent/Detergent	Pasteurization	Solvent/Detergent Heat Treatment 80°C x 72 hours	Solvent/Detergent treatment with a mixture of Tri (nbutyl) phosphate (TNBP) and Polysorbate 80/ Dry Heat Cycle at 80° for 72 hrs./Lyophilization
Degree of Purity	Ultra-High	4000 iu/mg protein	>4000 iu/mg protein	>4000 iu/mg protein	Intermediate	>2000 iu/mg	>2000 iu/mg	Ultra-High	Specific activity, after addition of human albumin is in the range of 9-22iu/mg protein	High Purity
Product Half-Life	13 hours	approximately 13 hours	14.6 ± 4.9 hours	Pivotal PH Study: Advate 11.98 ± 4.28 hr compared to Recombinate 11.24 ± 2.53	12.2 hours	14.8 ± 3 hours	14.8 ± 3 hours	17.5 hours	approximately 16 hours	17.9 ± 9.6 hours
Product Recovery Percentage	2% per iu/kg	2.1±0.3%/iu/kg mean SD t1/2 13.9 hours	2.4 % iu/dl/iu/kg	2.41 % iu/dl/iu/kg	1.5% per iu/kg	approximately 2.0 iu/dL per infused iu/kg body weight	approximately 2.0 iu/dL per infused iu/kg body weight	2% per iu/kg	Incremental in vivo recovery 10 minutes after Koate DVI infusion is 1.9% iu/kg. Mean t1/2= 16.12 hours	96.7 ± 14.5% at 10 min post - infusion
Source Plasma	Recombinate	Recombinate	N/A; a recombinate FVIII	N/A; a Plasma/Albumin-Free Method recombinate FVIII	Paid Donor Pool	Volunteer Donor Pool	Source Plasma (paid donor pool)	Paid Donor Pool	US donors (human plasma-derived product)	Paid Donor Pool
Storage Requirements	Refrigeration	Kogenate FS should be kept under refrigeration; however, it may be stored up to three months at room temperature not exceeding 25 C (77 F)	Refrigeration 2°-8°C(36°-46°F) or room temperature, not to exceed 30°C or 86°F	2°-8°C (36°-46°F). May be stored at room temperature, 22°-28°C (72°-82°F) for up to 6 months or until expiration date, whichever comes first.	Refrigerate or 6 months at room temperature	Refrigeration 2°-8°C(36°-46°F) or room temperature, not to exceed 30°C or 86°F	Refrigeration 2°-8°C(36°-46°F) or room temperature, not to exceed 30°C or 86°F	Refrigeration or at room temperature for 6 months	Refrigeration (2°-8°C); room temperature (up to 25°C) for 6 months	2°-8°C Do not freeze diluent, or room temperature not to exceed 30°C for 2 months
Shelf Life	23 months under refrigeration	23 months under refrigeration	36 months	24 months	2 years	30 months	30 months	2 years	24 months under refrigeration	2 years stored as directed
Diluent Volume	2.5ml	250iu- 5ml 500iu- 5ml 1000iu- 10ml	10ml	5ml	10ml, 20ml or 30ml	10ml	10ml	10ml or 20ml	250iu- 5ml 500iu-5ml 1000iu- 10ml	500iu-5ml 1000iu & 1500iu-10ml