Plasma-Derived Factor VIII

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Product Specifics	Alphanate® Grifols	Koate®-DVI Kedrion	Humate-P® CSL Behring	Monoclate-P® CSL Behring	Hemofil M Shire
Indications	Alphanate is indicated for: • Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with Factor VIII (FVIII) deficiency due to hemophilia A. • Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (Type 3) undergoing major surgery.	Hemophilia A in which there is a deficiency of clotting Factor VIII	Prevention and treatment of bleeding in adult patients with Hemophilia A. Also indicated for adult and pediatric patients with von Willebrand disease for (1) treatment of spontaneous and trauma-induced bleeding episodes and (2) prevention of excessive bleeding during and after surgery. This applies to patients with severe VWD as well as patients with mild to moderate VWD where use of desmopressin is known or suspected to be inadequate.	Hemophilia A	The use of HEMOFIL M NF is indicated in hemophilia A (classical hemophilia) for the prevention and control of hemorrhagic episodes.HEMOFIL M NF is not indicated in von Willebrand's disease.
Contraindications	Alphanate is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.	None known	Individuals who have had an anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations.	Known hypersensitivity to mouse protein	HEMOFIL M NF is contraindicated in patients with a known hypersensitivity to the active substance, to excipients, or to mouse proteins.
Source Plasma	Alphanate is manufactured using source plasma from qualified adult donors who are thoroughly screened and tested. Using the National Donor Deferral Registry (NDDR), previously rejected applicants will not be allowed to donate. Each source plasma donation undergoes a minimum 60-day inventory hold. When the inventory hold period is over, each donation is computer verified. Plasma is then pooled for production and tested again for HIV, HAV, HBV, HCV and PVB19. Repeating the viral testing for both individual donations and the production pools guarantees that each plasma donation has met all safety controls.	Plasma-derived. Koate®-DVI is made from large pools of human plasma donated at centers within the US.	Pooled human plasma	Pooled human plasma	Human
Viral Safety Processes	Affinity Chromatography, 3.5% PEG precipitation, salt/glycine precipitation, and lyophilization. Solvent/Detergent Treatment and Heat Treatment at 80° for 72 hrs. Manufacturing process includes steps that provide a reasonable assurance that low levels of a vCJD model agent, if present in the starting material, would be removed.	The following Koate®-DVI protein purification methods may provide virus removal: cryo-separation, adsorption, PEG precipitation, and gel permeation chromatography. Solvent/Detergent Treatment, Freeze Dry/Dry Heat Treatment at 80°C, 72 hours	Cryoprecipitation and Al(OH)3 adsorption, glycine precipitation and NaCl precipitation. Pasteurization in aqueous solution at 60°C for 10 hours	Monoclonal Antibody Immunoaffinity Chromatography. Pasteurization by heating at 60°C for 10 hours in aqueous solution	Immunoaffinity Chromatography, Ion Exchange Chromatography, Nanofiltration. Solvent/Detergent Treatment
Product Half Life	17.9 ± 9.6 hours in hemophilia A patients 7.67 ± 3.3 hours for VWF:RCo in VWD patients 21.6 ± 7.8 hours for FVIII:C in VWD patients	Mean half-life of 16.12 hours	Mean half-life of 12.2 hours in Hemophilia A patients, Median terminal half-life of VWF:RCo was 11 hours	Mean half-life of 17.5 hours	14.8 ± 3.0 hours
Product Recovery Percentage	96.7 ± 14.5% (mean ± SD) hours in hemophilia A patients 3.3 ± 1.5 (IU/dL)/(IU/kg) for VWF:RCo in VWD patients 2.1 ± 0.6 (IU/dL)/(IU/kg) for FVIII:C in VWD patients	Specific activity (9-22 IU/mg protein). Incremental in vivo recovery 10 minutes after Koate®-DVI Infusion is 1.9% IU/kg.	2%/IU/kg	2%/IU/kg	approximately 2.0 iu/dL per infused iu/kg body weight
Presence of von Willebrand Factor	Yes	Koate®-DVI contains naturally occuring von Willebrand factor, which is co-purified during the manufacturing process. Koate®-DVI is not indicated for the treatment of von Williebrand disease.	Yes, VWF:Rco to FVIII ratio: 2.4:1	Reduced amounts of VWF:Ag	No
Storage Requirements	Room tempertaure storage for 36 months, up to expiration date printed ≤77 °F	Refrigeration (2°-8°C; 36°-46°F); room temperature storage (up to 25°C or 77°F) of lyophilized (before reconstitution) powder for 6 months without loss of Factor VIII activity, such as in home treatment situations. Freezing should be avoided as breakage of the diluent bottle might occur.	When stored up to 25°C (up to 77°F), Humate-P® is stable up to the expiration printed on the label. Avoid freezing.	Store in refrigerator, 2-8°C (36-46°F) through expiration date on label. Within this period, Monoclate-P® may be stored at room temperature, not to exceed 25°C (77°F), for up to 6 months. Avoid freezing which may damage container for the diluent.	Refrigeration 2° - 8°C (36° - 46°F) or room temperature, not to exceed 30°C or 86°F until expiration date noted on package.
Shelf Life from Date of Manufacture	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).	24 months under refrigeration (see above). Do not use Koate®-DVI after the labeled expiration date.	36 months	24 months	30 months
How Supplied / Diluent Volume	5mL for 250 and 500 IU 10mL for 1000, 1500, and 2000 IU	250 IU – 5 mL, 500 IU – 5 mL, 1,000 IU – 10 mL	600 IU VWF:RCo/vial - 5 mL, 1,200 IU VWF:RCo/vial - 10 mL, 2,400 IU VWF:RCo/vial - 15 mL	250 IU - 2.5 mL, 500 IU - 5 mL, 1,000 IU - 10 mL, 1,500 IU - 10 mL	10 mL