Plasma-Derived Factor VIII

Product Specifics	Alphanate® Grifols	HEMOFIL M Shire	Humate-P® CSL Behring	KOĀTE® Kedrion	Monoclate-P® CSL Behring
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.	The use of HEMOFIL M is indicated in hemophilia A (classical hemophilia) for the prevention and control of hemorrhagic episodes. HEMOFIL M is not indicated in von Willebrand's disease.	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. Humate-P is not indicated for the prophylaxis treatment of spontaneous bleeding episodes in VWD.	KOĀTE is a human plasma-derived antihemophilic factor indicated for the control and prevention of bleeding episodes or in order to perform emergency and elective surgery in patients with hemophilia A.	Treatment of hemophilia A
Contraindications	Alphanate is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.	HEMOFIL M is contraindicated in patients with a known hypersensitivity to the active substance, to excipients, or to mouse proteins.	Individuals who have had an anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations.	Do not use in patients who have known hypersensitivity reactions, including anaphylaxis, to KOĀTE or its components.	Known hypersensitivity to mouse protein
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.	Human	Cold insoluble fraction of pooled human plasma	KOĀTE is made from human plasma donated at centers within the US.	Pooled human plasma
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.	Immunoaffinity Chromatography, Ion Exchange Chromatography, Nanofiltration. Solvent/Detergent Treatment	Cryoprecipitation and Al(OH)3 adsorption, glycine precipitation and NaCl precipitation, studied in combination. Heat treatment in aqueous solution at 60°C for 10 hours. Lyophilization	The KOĀTE manufacturing process includes two dedicated steps with virus inactivation capacity. The solvent/detergent treatment step has the capacity to inactivate enveloped viruses (such as HIV, HCV, HBV, and WNV). Heat treatment at 80°C for 72 hours has the capacity to inactivate enveloped viruses (such as HIV and HCV) as well as nonenveloped viruses (such as HAV and B19V). The polyethylene glycol (PEG) precipitation/depth filtration step has the capacity to remove both enveloped and nonenveloped viruses. The manufacturing process has been shown to decrease TSE infectivity of that experimental model agent (a total of 5.1 log10 reduction), providing reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed.	Monoclonal Antibody Immunoaffinity Chromatography. Pasteurization by heating at 60°C for 10 hours in aqueous solution
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	14.8 ± 3.0 hours	Hemophilia A: Mean half-life of 12.2 hours (8.4-17.4) VWF:RCo 11 hours (3.5-33.6)	Mean biologic half-life was 16.1 hours.	Mean half-life of 17.5 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	Approximately 2.0 iu/dL per infused iu/kg body weight	2 IU/dL/IU/kg	Each vial of KOĀTE is labeled with the actual Factor VIII potency in international units (IU). Calculation of the required dose of Factor VIII activity is approximately 2%	1.9 IU/dL/IU/kg
Presence of von Willebrand Factor	Yes	No	Yes, VWF:Rco to FVIII ratio: 2.4:1	Yes, but NOT indicated for Von Willebrand Disease	Reduced amounts of VWF:Ag
Storage Requirements	Room temperature storage for 36 months, up to expiration date printed ≤ 25 °C (77 °F). Do not Freeze.	Refrigeration 2° - 8°C (36° - 46°F) or room temperature, not to exceed 30°C or 86°F until expiration date noted on package.	When stored up to 25°C (up to 77°F), Humate-P® is stable up to the expiration printed on the label. Do not freeze.	Store the KOĀTE package at 2 to 8°C (36 to 46°F). KOĀTE may be stored at room temperature (up to 25°C or 77°F) for up to 6 months	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.
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).	30 months	36 months	Approximately 24 months. Do not use KOĀTE after the labeled expiration date.	24 months
How Supplied / Diluent Volume	5mL for 250 and 500 IU 10mL for 1000, 1500, and 2000 IU	10 mL	600 IU VWF:Rco and 250 IU FVIII/vial - 5 mL, 1,200 IU VWF:Rco and 500 IU FVIII/vial - 10 mL, 2,400 IU VWF:Rco and 1000 IU FVIII/vial - 15 mL	250 IU - 5mL, 500IU - 5mL and 1000mL 10IU with Mix2Vial	250 IU - 2.5 mL, 500 IU - 5 mL, 1,000 IU - 10 mL, 1,500 IU - 10 mL