

# Plasma-Derived Factor VIII



800.948.9834 ■ www.bdipharma.com

PRODUCT SPECIFICS	Koate®-DVI	Alphanate®	Humate-P®	Monoclate-P®	Hemofil M
INDICATIONS	Hemophilia A in which there is a deficiency of clotting Factor VIII	Alphanate® is indicated for: 1. Control and prevention of bleeding in patients with hemophilia A. 2. Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (Type 3) undergoing major surgery.	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	Prevention and control of bleeding episodes in patients with Hemophilia A; can be of therapeutic value in patients with FVIII inhibitors not exceeding 10 BU. See PI for additional details.
CONTRAINDICATIONS	None known	Alphanate® is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.	Individuals who have had an anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations.	Known hypersensitivity to mouse protein	Known hypersensitivity to mouse protein. See PI for additional details.
SOURCE PLASMA	Plasma-derived. Koate®-DVI is made from large pools of human plasma donated at centers within the US.	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.	Pooled human plasma	Pooled human plasma	Human
VIRAL REMOVAL PROCESS	The following Koate®-DVI protein purification methods may provide virus removal: cryo-separation, adsorption, PEG precipitation, and gel permeation chromatography	Affinity Chromatography, 3.5% PEG precipitation, salt/glycine precipitation, and lyophilization	Cryoprecipitation and Al(OH) <sub>3</sub> adsorption, glycine precipitation and NaCl precipitation	Monoclonal Antibody Immunoaffinity Chromatography	immunoaffinity chromatography, column chromatography, nanofiltration
VIRAL INACTIVATION PROCESS	Solvent/Detergent Treatment, Freeze Dry/Dry Heat Treatment at 80°C, 72 hours	Solvent/Detergent Treatment and Heat Treatment at 80° for 72 hrs	Pasteurization in aqueous solution at 60°C for 10 hours	Pasteurization by heating at 60°C for 10 hours in aqueous solution	Solvent/Detergent
PRODUCT HALF LIFE	Mean half-life of 16.12 hours	17.9 ± 9.6 hours in Hemophilia A patients 7.67 ± 3.3 hours for WWF:RCo in VWD patients 21.6 ± 7.8 hours for FVIII:C in VWD patients	Mean half-life of 12.2 hours in Hemophilia A patients, Median terminal half-life of WWF:RCo was 11 hours	Mean half-life of 17.5 hours	14/8 ± 3/0 hours
PRODUCT RECOVERY PERCENTAGE	Specific activity (9-22 IU/mg protein). Incremental in vivo recovery 10 minutes after Koate®-DVI infusion is 1.9% IU/kg.	96.7 ± 14.5% (mean ± SD) hours in Hemophilia A patients 3.3 ± 1.5 (IU/dL)/(IU/kg) for WWF:RCo in VWD patients 2.1 ± 0.6 (IU/dL)/(IU/kg) for FVIII:C in VWD patients	2%/IU/kg	2%/IU/kg	approximately 2.0 iu/dL per infused iu/kg body weight
PRESENCE OF VON WILLEBRAND FACTOR	Koate®-DVI contains naturally occurring von Willebrand factor, which is co-purified during the manufacturing process. Koate®-DVI is not indicated for the treatment of von Willebrand disease.	Yes	Yes	Reduced amounts of WWF:Ag	No
STORAGE REQUIREMENTS	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	Store at or below 25°C (77°F). Do not freeze.	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	24 months under refrigeration (see above). Do not use Koate®-DVI after the labeled expiration date	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).	2 years	24 months	30 months
DILUENT VOLUME	250 IU – 5 mL, 500 IU – 5 mL, 1000 IU – 10mL	250 IU and 500 IU - 5mL 1000 IU and 1500 IU - 10mL	600 IU WWF:RCo/vial - 5mL, 1200 IU WWF:RCo/vial - 10mL, 2400 IU WWF:RCo/vial - 15mL	250 IU - 2.5 mL, 500 IU - 5 mL, 1,000 IU - 10 mL, 1,500 IU - 10 mL	10 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.