

Product Specifics	Alphanate®	Koāte® - DVI	Humate-P®	Monoclate-P®	Hemofil M
Indications	Hemophilia A or acquired Factor VIII deficiency and von Willebrand Disease. Indicated for surgical and/or invasive procedures in patients with vWD in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for Type 3 vWD patients 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	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
Contraindications	None Known	None Known	Individuals with history of anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations. Also contraindicated in individuals with known hypersensitivity to any of its components.	Known hypersensitivity to mouse protein	Known hypersensitivity to mouse protein
Source Plasma	Grifols exclusively uses Source Plasma from qualified repeat donors at FDA inspected and IQPP certified donor centers in the US.	Plasma-derived. Koāte®-DVI is made from large pools of human plasma donated at centers within the US.	Pooled human fresh-frozen plasma	Pooled human plasma	human
Viral Removal Process	Affinity Chromatography, 3.5% PEG precipitation, salt/glycine precipitation, and lyophilization	The following Koāte®-DVI protein purification methods may provide virus removal: cryo-separation, absorption, PEG precipitation, and gel permeation chromatography	Cryoprecipitation and Al(OH) ₃ adsorption, glycine precipitation and NaCl precipitation	Monoclonal Antibody Immuno-Affinity Chromatography	Immuno-Affinity chromatography, ion exchange chromatography
Viral Inactivation Process	Solvent/Detergent Treatment and Heat Treatment at 80° for 72 hours	Solvent/Detergent Treatment, Freeze Dry/Dry Heat Treatment at 80°C, 72 hours.	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	17.9 ± 9.6 hours in hemophilia A patients 7.5 ± 3.2 hours for vWF:RCof in vWD patients 21.5 ± 7.2 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:RCof 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 Koāte®-DVI infusion is 1.9% iu/kg	2% iu/kg	2% per iu/kg	approximately 2.0 iu/dL per infused iu/kg body weight
Presence of von Willebrand Factor	Yes	Koāte®-DVI contains naturally occurring von Willebrand's factor, which is co-purified during the manufacturing process. Koāte®-DVI is not indicated for the treatment of von Willebrand's Disease.	Yes	Reduced amounts of vWF:Ag	No
Storage Requirements	2°-8°C. Do not freeze diluent. Stable at room temperature not to exceed 30°C for 2 months.	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	2 years	24 months under refrigeration (see above). Do not use Koāte®-DVI after the labeled expiration date	2 years	24 months	30 months
Diluent Volume	250 iu and 500 iu - 5 mL 1000 iu and 1500 iu - 10 mL	250 iu - 5 mL 500 iu - 5 mL 1000 iu - 10 mL	250 iu FVIII/vial - 5 mL, 500 iu FVIII/vial - 10 mL, 1000 iu FVIII/vial - 15 mL	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. Updated September 2008. ©2008. BDI Pharma, Inc. All rights reserved.