

# FVIII / vWF Complex Concentrates

[ Indicated to treat von Willebrand Disease ]



800.948.9834 ■ www.bdipharma.com

PRODUCT SPECIFICS	Alphanate®	Humate-P®	wilate®
INDICATIONS	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.	wilate® is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated for the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease (vWD) as well as patients with mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated.
CONTRAINDICATIONS	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.	Hypersensitivity with known anaphylactic or severe systemic reaction to human plasma-derived products, any ingredient in the formulation, or components of the container.
RATIO OF vWF:RCO TO FVIII	1.26 ± 0.28 based on 245 commercially available lots manufactured in sequence since 2007. Actual FVIII and vWF:RCo potency is listed on the vial label and folding carton for each lot.	2.4:1 vWF:RCo to FVIII	1:1 vWF:RCo to FVIII
VIRAL REMOVAL PROCESS	Affinity Chromatography, 3.5% PEG precipitation, salt/glycine precipitation, and lyophilization	Cryoprecipitation and Al(OH) <sub>3</sub> adsorption, glycine precipitation and NaCl precipitation	Ion-Exchange Chromatography
VIRAL INACTIVATION PROCESS	Solvent/Detergent Treatment and Heat Treatment at 80° for 72 hrs	Pasteurization in aqueous solution at 60°C for 10 hours	Solvent Detergent Treatment Terminal Dry Heat 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 12.2 hours in Hemophilia A patients, Median terminal half-life of vWF:RCo was 11 hours	15.8 ± 11.0 hrs (vWF) 19.6 ± 6.9 hrs (FVIII)
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	2%/IU/kg	2.0 ± 0.5 (vWF) 2.2 ± 0.5 (FVIII)
STORAGE REQUIREMENTS	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 wilate® for up to 36 months at +2°C to +8°C (36°F to 46°F), protected from light, from the date of manufacture. Within this period, wilate® may be stored for a period of up to 6 months at room temperature (maximum of +25°C or 77°F). Do not freeze.
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).	2 years	36 months
DILUENT VOLUME	250 IU and 500 IU - 5mL 1000 IU and 1500 IU - 10mL	600 IU vWF:RCo/vial - 5mL, 1200 IU vWF:RCo/vial - 10mL, 2400 IU vWF:RCo/vial - 15mL	500 IU vWF:RCo and 500 IU FVIII activities in 5 mL 1000 IU vWF:RCo and 1000 IU FVIII activities in 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.