

Product Specifics	Alphanate®	Humate-P®
Indications	<p>Hemophilia A or acquired Factor VIII deficiency and von Willebrand Disease.</p> <ul style="list-style-type: none"> 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. 	<p>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.</p>
Contraindications	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.
Ratio of vWF:RCo to FVIII	1.03 ± 0.17 based on 61 commercially available lots manufactured in sequence in 2007 Actual FVIII and vWF:RCof potency is listed on the vial label and folding carton	2.4:1 vWF:RCo to FVIII
Viral Removal Process	Affinity Chromatography, 3.5% PEG precipitation, salt/glycine precipitation, and lyophilization	Cryoprecipitation and Al(OH) ₃ adsorption, glycine precipitation and NaCl precipitation
Viral Inactivation Process	Solvent/Detergent Treatment and Heat Treatment at 80° for 72 hours	Pasteurization in aqueous solution at 60°C for 10 hours
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 12.2 hours in Hemophilia A patients, Median terminal half-life of vWF:RCo was 11 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	2% iu/kg
Storage Requirements	2°-8°C. Do not freeze diluent. Stable at room temperature not to exceed 30°C for 2 months.	When stored up to 25°C (up to 77°F), Humate-P® is stable up to the expiration printed on the label. Avoid freezing.
Shelf Life from Date of Manufacture	2 years	2 years
Diluent Volume	250 iu and 500 iu - 5 mL 1000 iu and 1500 iu - 10 mL	250 iu FVIII/vial - 5 mL, 500 iu FVIII/vial - 10 mL, 1000 iu FVIII/vial - 15 mL