FVIII / vWF Complex Concentrates (Indicated to treat von Willebrand Disease)

Product Specifics	Alphanate® Grifols	Humate-P® CSL Behring	VONVENDI® Shire	wilate® Octapharma
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.	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.	VONVENDI is a recombinant von Willebrand factor (VWF) indicated for on-demand treatment and control of bleeding episodes in adults diagnosed with von Willebrand disease.	WILATE is indicated in children and adults with von Willebrand disease for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding Limitations of Use: WILATE is not indicated for the 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.	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 had life-threatening hypersensitivity reactions to VONVENDI or its components (mannitol, trehalose, sodium chloride, histidine, Tris, calcium chloride, polysorbate 80, and hamster or mouse proteins).	WILATE is contraindicated in patients with known hypersensitivity reactions, including anaphylactic or severe systemic reactions, to human plasma-derived products, any ingredient in the formulation or components of the container
Viral Safety Processes	1.2 average ratio. Ratio of VWF:RCo to FVIII varies by lot, so check IU VWF:RCo/vial to ensure accurate dosing. Actual FVIII and VWF:RCo potency is listed on vial label & folding carton for each lot.	Cold insoluble fraction of pooled human plasma	Administer VONVENDI with recombinant factor VIII if required, to control bleeding. Dosing should be at a ratio of 1.3:1	The VWF:RCo to FVIII:C ratio is 1:1.
Product Half Life	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.	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	VONVENDI is produced and formulated without the addition of any exogenous raw materials of human or animal origin in the cell culture, purification, or formulation of the final product.	Ion-exchange chromatography, Solvent/detergent (S/D) treatment, and terminal dry-heat (TDH) treatment of the lyophilized product in final container [at +100°C (212°F) for 120 minutes at a specified residual moisture level of 0.7 - 1.6%].
Product Recovery Percentage	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	Hemophilia A: Mean half-life of 12.2 hours (8.4-17.4) VWF:RCo 11 hours (3.5-33.6)	Mean half-life of 19.3 hours when infused with ADVATE	15.8 ± 11.0 hours for VWF:RCo, and 19.6 ± 6.9 hours for FVIII:C.
Manufacturing Method	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/dL/IU/kg	1.7	1.9 ± 0.4 % per IU/kg for VWF:RCo, and 2.2 ± 0.5 % per IU/kg for FVIII:C.
Storage Requirements	Room temperature storage for 36 months, up to expiration date printed ≤ 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. Do not freeze.	Store VONVENDI refrigerated at 2°C to 8°C (36°F to 46°F) in the original box and protect from extreme exposure to light. Do not freeze. May store at room temperature up to 30°C (86°F) for a period of up to 12 months not to exceed the expiration date. Record on the carton the date VONVENDI is removed from refrigeration. Do not return to refrigerated temperature after storing at room temperature. Do not use beyond the expiration date printed on the VONVENDI vial label or carton.	Do not freeze. Do not use after expiration date.
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).	36 months	Use up to the expiration date on the label – may store for 12 months at room temperature not to exceed 30°C (86°F).	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).
How Supplied / Diluent Volume	5mL for 250 and 500 IU 10mL for 1000, 1500, and 2000 IU	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	450–850 IU in 5 mL, 900–1700 IU in 10 mL	500 IU VWF:RCo and 500 IU FVIII:C activities in 5 mL, and 1000 IU VWF:RCo and 1000 IU FVIII:C activities in 10 mL