

FVIII/vWF Products Comparison Table

I. MEDICAL / CLINICAL INFORMATION		
PRODUCTS ATTRIBUTES	HUMATE-P [®] , CSL BEHRING (Reduced volume formulation) Antihemophilic Factor/von Willebrand Factor Complex (Human), Dried, Pasteurized	WILATE [®] , OCTAPARMA Human Coagulation Factor VIII (FVIII) and Human von Willebrand Factor (VWF)
Indications	<ul style="list-style-type: none"> • Indicated in adult patients for treatment and prevention of bleeding in hemophilia A (classical hemophilia). • Indicated in adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate. • Indicated in von Willebrand disease to prevent excessive bleeding during and after surgery in adult and pediatric patients. 	<ul style="list-style-type: none"> • Indicated for treatment and prophylaxis of bleeding in patients with hemophilia A (congenital or acquired FVIII deficiency) and for the prevention and treatment of bleeding in minor surgical procedures.
Administration	Intravenous infusion	Intravenous infusion
Infusion rate	Up to 4 mL/minute	2-3 mL/minute
Dosage (for life-threatening hemorrhage and/or major surgery)	<ul style="list-style-type: none"> • Hemophilia A: Initially to 40-50 IU FVIII:C/kg, followed by 20-25 IU FVIII:C/kg every 8 hours to maintain FVIII:C plasma level at 80-100% of normal for 7 days, then continue the same dose once or twice a day for another 7 days in order to maintain the FVIII:C level at 30-50% of normal. • von Willebrand disease (types 2 & 3): 40-80 IU vWF:RCof/kg every 8 -12 hours for 3 days to keep the nadir level of vWF:RCof >50%, then 40 to 60 IU/kg daily for a total of up to 7 days of treatment. 	<ul style="list-style-type: none"> • Hemophilia A (pre- and postoperative): 80-100 IU/dl every 8-24 hours until adequate wound healing, then therapy for at least another 7 days to maintain a FVIII activity of 30% to 60%.
Half-life (<i>in vivo</i>)	<ul style="list-style-type: none"> • In Hemophilia A patients: 12.2 hours (range: 8.4-17.4 hours) • In VWD patients (all types, non-bleeding state) 10.3 hours (range: 6.4-18.6 hours) 	<ul style="list-style-type: none"> • In Hemophilia A patients: 14.8 hours ± 3.1
Contraindications	<ul style="list-style-type: none"> • None known, caution is advised in patients with known allergic reaction to constituents of the preparation. 	<ul style="list-style-type: none"> • Known hypersensitivity to this drug or to any ingredient in the formulation or component of the container.

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II. FORMULATION DATA		
PRODUCTS ATTRIBUTES	HUMATE-P®, CSL BEHRING (Reduced volume formulation) Antihemophilic Factor/von Willebrand Factor Complex (Human), Dried, Pasteurized	WILATE®, OCTAPARMA Human Coagulation Factor VIII (FVIII) and Human von Willebrand Factor (VWF)
Formulation	Lyophilized concentrate	Lyophilized concentrate
Diluent	Pyrogen-free water (provided)	Water for Injection with 0.1% Polysorbate 80 (provided)
Vial size (potency)	<ul style="list-style-type: none"> • 500/1200 IU FVIII:C/vWF:RCof to be reconstituted with 10 mL of diluent • 1000/2400 IU FVIII:C/vWF:RCof to be reconstituted with 15 mL of diluent 	<ul style="list-style-type: none"> • 450 IU FVIII / 400 IU VWF to be reconstituted with 5 mL of diluent • 900 IU FVIII / 800 IU VWF to be reconstituted with 10 mL of diluent
Concentration	Upon reconstitution: <ul style="list-style-type: none"> • 50/120 IU/mL for the 500/1200 IU FVIII:C/vWF:RCof vial size • 67/160 IU/mL for the 1000/2400 IU FVIII:C/vWF:RCof vial size 	Upon reconstitution: 90 IU/mL FVIII / 80 IU/mL VWF
Specific activity	Not indicated	≥ 60 IU FVIII:C/mg of total protein and ≥ 53 IU VWF:RCo/mg of total protein
Storage requirements	Store at room temperature, up to 25°C, for the period indicated by the expiration date on its label.	2-8 °C until the indicated expiry date or for a single block of up to 6 months at room temperature (max. +25 °C) within this period. Protect from light.
Relevant non medical ingredients	<ul style="list-style-type: none"> • Albumin 8-16 mg/mL • Glycine 15-33 mg/mL • Sodium citrate 3.5-9.3 mg/mL • Sodium chloride 2-5.3 mg/mL • Aluminum <0.1 µg/mL • Other protein 2-14 mg/mL 	<ul style="list-style-type: none"> • Glycine • Sucrose • Sodium citrate • Sodium chloride • Calcium chloride • No additional stabilizing proteins added during production
Sodium content	<ul style="list-style-type: none"> • Sodium citrate 3.5-9.3 mg/mL • Sodium chloride 2-5.3 mg/mL 	<ul style="list-style-type: none"> • Sodium citrate • Sodium chloride
Sugar content	None indicated	Sucrose
Viral inactivation	<ul style="list-style-type: none"> • Pasteurization process (10 hours at 60 °C in aqueous stabilized solution) 	<ul style="list-style-type: none"> • Solvent/Detergent treatment • Dry heat treatment in final container at +100°C for 120 minutes
Note: Only significant reduction steps are listed i.e. steps removing 4 Log or greater – enveloped viruses		

Reference Canadian Monographs Approval Dates:
 Humate-P®, October 9, 2009
 wilate®, July 13, 2009