### FVIII/vWF Products Comparison Table

**I. MEDICAL / CLINICAL INFORMATION**

| PRODUCTS | **HUMATE-P®, CSL BEHRING** (Reduced volume formulation) Anthemophilic Factor/von Willebrand Factor Complex (Human), Dried, Pasteurized | **WILATE®, OCTAPHARMA** Human Coagulation Factor VIII (FVIII) and Human von Willebrand Factor (VWF) |
| Attributes | | |
| Indications | • Indicated in adult patients for treatment and prevention of bleeding in hemophilia A (classical hemophilia).<br>• 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 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) | • 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.<br>• 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. | • 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 (in vivo) | • In Hemophilia A patients: 12.2 hours (range: 8.4-17.4 hours)<br>• In VWD patients (all types, non-bleeding state) 10.3 hours (range: 6.4-18.6 hours) | • In Hemophilia A patients: 14.8 hours ± 3.1 |
| Contraindications | • None known, caution is advised in patients with known allergic reaction to constituents of the preparation. | • Known hypersensitivity to this drug or to any ingredient in the formulation or component of the container. |
## II. FORMULATION DATA

<table>
<thead>
<tr>
<th>PRODUCTS</th>
<th><strong>HUMATE-P®, CSL BEHRING</strong></th>
<th><strong>WILATE®, OCTAPHARMA</strong></th>
</tr>
</thead>
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**Formulation**
- Lyophilized concentrate
- Lyophilized concentrate

**Diluent**
- Pyrogen-free water (provided)
- Water for Injection with 0.1% Polysorbate 80 (provided)

**Vial size (potency)**
- **HUMATE-P®**:
  - 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
- **WILATE®**:
  - 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:
  - 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**
- 2-8 °C for the period indicated by the expiration date. Within this period, may be stored at room temperature, not to exceed 30 °C, for up to six months.
- 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**
- 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 <0.5 µg/mL
- Other protein 2-14 mg/mL
- Glycine
- Sucrose
- Sodium citrate
- Sodium chloride
- Calcium chloride
- No additional stabilizing proteins added during production

**Sodium content**
- Sodium citrate 3.5-9.3 mg/mL
- Sodium chloride 2-5.3 mg/mL
- Sodium citrate
- Sodium chloride

**Sugar content**
- None indicated
- Sucrose

**Viral inactivation**
- Pasteurization process (10 hours at 60 °C in aqueous stabilized solution)
- 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®, September 26, 2007
wilate®, November 28, 2007