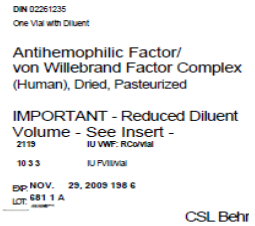
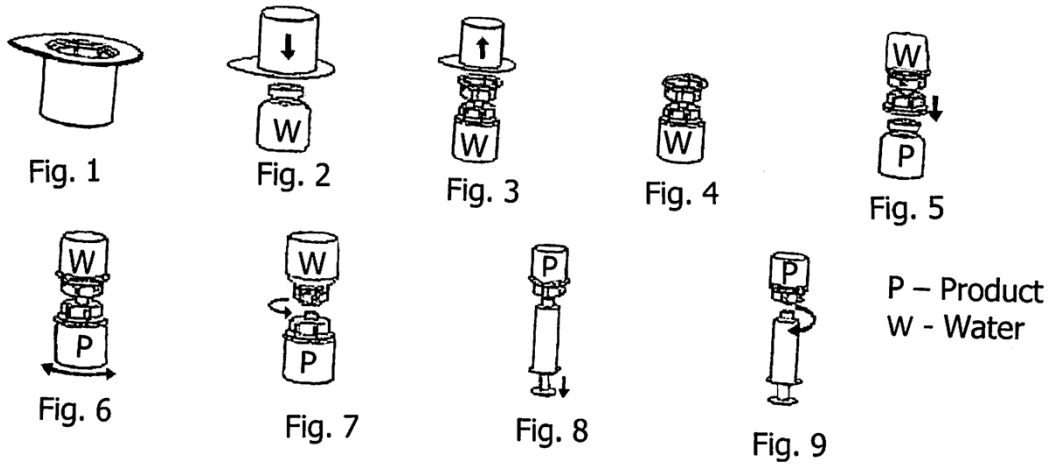
Other Names	• Antihemophilic factor/von Willebrand Factor
Description	• Human, dried, pasteurized, stable, purified, sterile, lyophilized concentrate of Antihemophilic Factor and von Willebrand factor

Special Approvals/Authorizations	• An independent 2 person check is required for all doses. Nurses from the Manitoba Bleeding Disorder Program are exempt from the independent 2 person check.
	• A nurse may administer a dose that provides:
	  ○ Up to 200 units greater than the prescribed dose; or
	  ○ No more than 100 units less than the prescribed dose without receiving a new medication order.
	• Patients accustomed to self-administering factor may continue to do so on the written order of a hematologist or designate.

Classification	**Special Populations:** **Pediatrics:** Safety, efficacy for treatment of von Willebrand disease has been demonstrated in pediatric patients but not yet been evaluated in neonates. Adequate and well-controlled studies with long term evaluation of joint damage in hemophilia have not yet been done. General recommendations for dosing and administration for adults should be referenced for bleeding in children for Hemophilia A. **Nursing mothers:** Not known whether Humate P is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Humate P is administered to a nursing woman. **Pregnant women:** Animal reproduction studies have not been conducted. Humate P should be used in pregnancy only if clearly needed and the expected benefit outweighs any potential risk.
Indications	• For the treatment and prevention of bleeding in adult patients with hemophilia A. • For treatment of spontaneous and trauma-induced bleeding episodes in adults and pediatric patients with severe von Willebrand disease or in mild and moderate von Willebrand disease where use of desmopressin • To prevent excessive bleeding during and after surgery in adult and pediatric patients.
Contraindications	• Contraindicated in individuals who have known allergic reaction to constituents of the preparation. **WARNINGS:** • Serious thromboembolic events have been reported in patients with von Willebrand disease. • Humate P is made from human plasma. Products made from large pools of human plasma may contain infectious agents including hepatitis and other viruses that can cause disease. • When very large or frequently repeated doses are needed, as when inhibitors are present or when pre and post surgical care is involved, patients of blood groups A, B and AB should be monitored for signs of intravascular hemolysis and decreasing hematocrit values.
Supplied	Vial size is 1000 international units and 2000 international units.
Dosage	**Note: Dosing in von Willebrand disease is calculated as RiCof units and in Hemophilia A is calculated as FVIII.** **Recommended dose and dose adjustment in von Willebrand disease:** **Patient response and lab monitoring guide dosing.** Mild/Moderate Hemorrhage: 40-50 *vWF/Riscof units/kg/dose* Major/Life-Threatening Hemorrhage: 40-60 *vWF/Riscof units/kg/dose* Minor Surgery: 40-50 *vWF/RisCof units/kg/dose* Major Surgery: 80-100 *vWF/RisCof units/kg/dose*

	Recommended dose and dose adjustment in Hemophilia A: **Patient response and lab monitoring guide dosing. 1 unit/kg usually raises FVIII level by 2% (international units/dL) of normal activity** Mild/Moderate Hemorrhage: 15-25 FVIII units/kg Major/Life Threatening Hemorrhage: 40-50 FVIII units/kg Major Surgical Procedures: 20-50 FVIII units/kg **MEDICATION ERROR ALERT**  DIN 02261235 One Vial with Diluent Antihemophilic Factor/ von Willebrand Factor Complex (Human), Dried, Pasteurized IMPORTANT - Reduced Diluent Volume - See Insert - 2119 IU VWF: RCo/Vial 1033 IU FVIII/Vial Exp NOV. 29, 2009 198 6 LOT 681 1 A CSL Behr READ HERE FOR vWF:RisCof units/vial
Reconstitution/Stability	**Reconstitution:** 1. Ensure that the Humate P vial and diluent vial are at room temperature. 2. Place the Humate P vial, diluent vial and Mix2Vial transfer set on a flat surface. 3. Remove the Humate P and diluent vial caps and wipe the stoppers with alcohol. Allow to dry prior to opening the Mix2Vial transfer set in the package. 4. Open the Mix2Vial transfer set package by peeling away the lid (fig. 1). Leave the Mix2Vial transfer set in the clear package. 5. Place the diluent vial on a flat surface and hold the vial tightly. Grip the Mix2Vial transfer set together with the clear package and push the plastic spike at the blue end of the Mix2Vial transfer set firmly through the center of the stopper of the diluent vial (fig. 2) 6. Carefully remove the clear package from the MixVial transfer set. Make sure that you pull up only the package and not the Mix2Vial transfer set (fig 3). 7. With the Humate P vial placed firmly on a flat surface (fig. 4), invert the diluent vial with the Mix2Vial transfer set attached and push the plastic spike of the transparent adapter firmly through the center of the stopper of the Humate P vial (fig. 5). The diluent will automatically transfer into the Humate P vial. 8. With the diluent and Humate P vial still attached to the Mix2Vial transfer set, gently swirl the Humate P vial to ensure the Humate P is fully dissolved (fig. 6). Do not shake. 9. With one hand grasp the Humate P side of the Mix2Vial transfer set and with the other hand grasp the blue diluent side of the Mix2Vial transfer set, and unscrew the set carefully into two pieces to avoid excessive buildup of foam when dissolving Humate P (fig. 7). 10. Draw air into an empty, sterile syringe. While the Humate P vial is upright, screw the syringe to the Mix2Vial transfer set. Inject air into the Humate P vial. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly (fig. 8). 11. Firmly grasp the barrel of the syringe (keeping the syringe plunger facing down) and unscrew the syringe from the Mix2Vial transfer set (fig. 9). Attach the syringe to a suitable intravenous administration set. 12. If patient requires more than one vial, pool the contents of multiple vials into one syringe. Use a separate unused Mix2Vial for each product vial.

	 Fig. 1 Fig. 2 Fig. 3 Fig. 4 Fig. 5 Fig. 6 Fig. 7 Fig. 8 Fig. 9 **Stability** • When stored at room temperature, up to 25 °C Humate P is stable for the period indicated by the expiration date on its label. • Do not freeze. • Infusions should be completed within 3 hours after reconstitution of the product. • Do NOT administer concurrently with any other medicinal product.
Compatibilities/ Incompatibilities	• No other drugs / solutions (including normal saline) can be co-administered in the same line while Humate P is being infused
Administration, Identification and ABO Compatibility	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration • ABO compatibility not applicable
Administration, Method	**Maximum Concentration:** • Not applicable **Maximum Rate for Infusion:** • 4 mL/minute
Adverse Events	**ADVERSE REACTIONS REPORTED:** ALLERGIC REACTIONS: urticaria, chest tightness, rash, pruritis and edema GENERAL DISORDERS Phlebitis, vasodilation, paresthesia, pseudo-thrombocytopenia BODY AS WHOLE Pain, fever, abdominal pain, infection, surgery, back pain, facial edema GASTROINTESTINAL DISORDERS Nausea, constipation, vomiting, sore throat CARDIOVASCULAR DISORDERS Chestpain, pulmonary embolus, thrombophlebitis LYMPHATIC DISORDERS Anemia, decreased hemoglobin NERVOUS DISORDERS Dizziness, headache, increased sweating, insomnia RENAL and URINARY Urinary tract infection
References:	Humate P Product Monograph – Date of Approval: March 11, 2014 Highlights of Prescribing Information – Revised: June 2014
Reviewed By:	Dr. Donald Houston Dr. Jayson Stoffman