HUMATE-P® (Antihemophilic Factor/von Willebrand Factor Complex [Human])

ADMINISTRATION SUPPLIES REQUIRED

- Intravenous infusion catheter set*
- Sterile syringe*
- Alcohol wipes*
- Sharps container*
- Gloves (if recommended by the healthcare provider) *
- Sterile Water for Injection, USP†
- Mix2Vial filter transfer set†

*Not supplied by CSL Behring with HUMATE-P
†Supplied by CSL Behring with HUMATE-P

ADMINISTRATION

- Intravenous use after reconstitution only.
- Reconstitute HUMATE-P at room temperature prior to use using Sterile Water for Injection, USP.
- Use either the Mix2Vial® filter transfer set provided with HUMATE-P or a commercially available double-ended needle and vented filter spike for reconstitution.
- Use a plastic disposable syringe with HUMATE-P. Protein solutions of this type tend to adhere to the ground glass surface of all-glass syringes.
- Slowly infuse the solution (maximally 4 mL/minute) with a suitable intravenous administration set.
- Administer HUMATE-P at room temperature and within 3 hours after reconstitution.

HOW SUPPLIED

HUMATE-P is supplied in a single-use vial containing the labeled amount of VWF:RCo and FVIII activity expressed in International Units (IU). Each product presentation includes a package insert and the following components:

Table 1. How Supplied

Presentation	Carton NDC Number	Components
600 IU VWF:RCo and 250 IU FVIII	63833-615-02	• HUMATE-P in a single-dose vial [NDC 63833-625-01] • 5 mL vial of Sterile Water for Injection, USP [NDC 63833-765-53] • Mix2Vial transfer set
1200 IU VWF:RCo and 500 IU FVIII	63833-616-02	• HUMATE-P in a single-dose vial [NDC 63833-626-01] • 10 mL vial of Sterile Water for Injection, USP [NDC 63833-765-54] • Mix2Vial transfer set
2400 IU VWF:RCo and 1000 IU FVIII	63833-617-02	• HUMATE-P in a single-dose vial [NDC 63833-627-01] • 15 mL vial of Sterile Water for Injection, USP [NDC 63833-765-55] • Mix2Vial transfer set

Indication

Antihemophilic Factor/von Willebrand Factor Complex (Human), HUMATE-P® is indicated for treatment and prevention of bleeding in adult patients with hemophilia A (classical hemophilia). HUMATE-P is also indicated in adult and pediatric patients with von Willebrand disease (VWD) 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, and patients with mild and moderate VWD for whom use of desmopressin is known or suspected to be inadequate. HUMATE-P is not indicated for the prophylaxis of spontaneous bleeding episodes.

The material provided is for informational purposes only. CSL Behring does not endorse specific devices, needles, or supplies and is not responsible for any omissions or accuracy of the product information. This may not be a complete list of vendors that supply the products below. The product manufacturer should be contacted for information and questions regarding their specific ancillary supplies. The products listed in the following tables have not been tested by CSL Behring.

HUMATE-P®
Antihemophilic Factor/von Willebrand Factor Complex (Human)

Intravenous Infusion Set*

Table 1. Manufacturers of Intravenous Infusion Sets

Product Name	Manufacturer	Contact
Infusion Set McKesson Prevent®	McKesson	855-571-2100
SURFLO® Winged Infusion Sets	Terumo Medical Products	800-888-3786
Safety Scalp Vein Set Safety PSV/Butterfly/Small Vein Infusion	Exel	310-649-0707

If you have a medical information question, please call 1-800-504-5434 or email the Medical Information Mailbox at MedinfoNA@cslbehring.com.

Trademarks of ancillary supplies are the property of their respective owners. *Not an all-inclusive list.

Important Safety Information

Monitor for intravascular hemolysis and decreasing hematocrit values in patients with A, B, and AB blood groups who are receiving large or frequent doses. Also monitor VWF:RCo and FVIII levels in VWD patients, especially those undergoing surgery.

Thromboembolic events have been reported in VWD patients receiving coagulation factor replacement. Caution should be exercised and antithrombotic measures considered, particularly in patients with risk factors for thrombosis.

HUMATE-P is derived from human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In patients receiving HUMATE-P in clinical studies for treatment of VWD, the most commonly reported adverse reactions (reported by >5% of subjects) were allergic-anaphylactic reactions, including urticaria, chest tightness, rash, pruritus, and edema. For patients undergoing surgery, the most common adverse reactions are postoperative wound or injection-site bleeding, and epistaxis.

Please see full prescribing information for HUMATE-P.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.