ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Humate P®
Factor VIII/vWF Complex (human)

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *Human Factor VIII/von Willebrand Factor Complex* ***Company:*** *CSL Behring* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

**** Direct IV Administration of Blood Products may be performed by professionals per the Transfusion of Blood Components and Products Learning Module. Not to be confused with medication administration.**

DESCRIPTION:

- Humate-P® is a stable, lyophilized concentrate of Antihemophilic factor and von Willebrand Factor (vWF) purified from pooled human fresh-frozen plasma.
- Virally reduction/inactivation steps include cryoprecipitation, adsorption, precipitation, and pasteurization.
- Humate-P® has a high degree of purity with a low amount of non-factor proteins.
- Each Humate-P® vial contains the labeled amount of Factor VIII and vWF:RCoF activity expressed in international units (IU).
- Reconstituted solution is clear or slightly opalescent.
- Available in 1000 RcoF IU, and 2000 RcoF IU single-use vials.
- Vials are reconstituted with sterile water for injection (10mL and 15mL respectively).
- pH is 6.8-7.4.
- Also contains albumin, glycine, sodium chloride, sodium citrate.
- Preservative free.
- Latex-free.

AVAILABILITY

- Supplied by Canadian Blood Services.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS:

- Adult patients for treatment and prevention of bleeding in hemophilia A (other products are available for this indication and may be preferred).
- Adult and pediatric patients with von Willebrand disease for:
  - Treatment of spontaneous and trauma-induced bleeding episodes.
  - Prevention of excessive bleeding during and after surgery.
- This applies to patients with severe, as well as mild to moderate vWD, where use of desmopressin (DDAVP) is known or suspected to be inadequate.

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations, or any ingredient in the formulation or components of the container.

WARNINGS:

- Thromboembolic events have been reported in vWD patients receiving coagulation factor replacement therapy, especially in the setting of known risk factors for thrombosis. Caution should be exercised, and anti-thrombotic measures should be considered in these patients.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MRHP) only after consult with Hematologist or bleeding disorders clinic.
- Dose issued may slightly vary (+/- 10%) from dose ordered (based on vial sizes).
- Each vial of Humate-P® contains the labeled amount of Factor VIII activity in IU for the treatment of hemophilia A. It is important to calculate the dose using the number of IU of FVIII:C specified.
- **Therapy for Hemophilia A:**
  - Dosage must be individualized based on patient-specific factors including weight, severity of hemorrhage, and presence of inhibitors.
  - Consult package insert for dose recommendations.
- **Therapy for von Willebrand Disease:**
  - Consult with Hematologist or local rare bleeding disorders clinic.
- **On-demand treatment:**
  - Refer to patient's care plan or Factor First card, if available.
  - If neither are available, consult with bleeding disorders clinic or transfusion medicine physician.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight is on file.
- Ensure pertinent labs are available as required.
- Ensure any ordered pre-medications have been given.
- Perform the appropriate pre-transfusion checks per AHS Transfusion of Blood Components and Blood Products Policy.
- Report any new onset acute illness to the authorized prescriber prior to starting infusion.

Access: Peripheral or central venous access site.

Reconstitution Supplies:

- Humate-P® Product (lyophilized powder)
- Diluent (sterile water for injection, included with product)
- Mix2Vial filter transfer set (included with product)
- Sterile plastic Luer lock syringe, large enough to contain dose.
- Alcohol swabs

Reconstitution:

- Bring Humate-P® and diluent vial to room temperature before reconstitution.
- See *Mix2Vial Reconstitution Instructions.*
- Humate-P® should be visually inspected for particulate matter and discoloration prior to administration. Do not use visibly cloudy solutions or solutions still containing flakes or particles after filtration.
- Do not refrigerate after reconstitution.

Compatible IV Solutions:

- Humate-P should not be mixed with other medicinal products or solutions.
- Normal saline can be used to flush the line.

Administration Supplies:

- **Direct IV administration:**
  - Sterile plastic syringe (large enough to contain dose)
- **IV infusion:**
  - IV administration set
  - IV pump

* Note: Humate-P can be administered through an administration set without a filter since filtering is achieved through reconstitution with the Mix2Vial device.

Administration:

- Administer within 3 hours after reconstitution.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Maximum rate is 4 mL/min or as requested by the ordering physician or bleeding disorders clinic.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Blood Products Policy.
- Start and stop time of infusion and assessment of patient tolerability should be documented in appropriate clinical record (electronic or paper).
- Document vital signs as required in the appropriate clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- The most commonly reported adverse reactions in patients receiving Humate-P® are allergic-anaphylactic reactions (including urticaria, chest tightness, rash, pruritis, edema, and shock).

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	**Action:** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- Store at 2-25°C until expiry.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

CSL Behring Canada, Inc. May 2019. Humate-P® Product Monograph. Control # 224286. [Accessed 12Nov21]. https://labeling.cslbehring.ca/PM/CA/Humate-P/EN/Humate-P-Product-Monograph.pdf

Transfusion of Blood Components and Blood Products. AHS Policy PS-9.