Alberta Health Services

This document applies to all Covenant and AHS sites.

Humate-P®

Class: *Manufactured antihemophilic factor,, derived from human plasma*

OTHER NAMES: Human Factor VIII/von Willebrand Factor Complex

Company: CSL Behring

	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.**

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**

DESCRIPTION OF PRODUCT:

- Humate-P® is a stable, lyophilized concentrate of Antihemophilic factor and von Willebrand Factor (vWF) purified from pooled human fresh-frozen plasma.
- Virally reduced by 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).
- Dispensed in 1000 RcoF IU, and 2000 RcoF IU vials.
- **Latex-free**

AVAILABILITY:

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

INDICATIONS FOR USE:

- 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:
  (1) Treatment of spontaneous and trauma-induced bleeding episodes.
  (2) 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.
- Known hypersensitivity or allergic reaction to any of the constituents in the preparation of Humate-P®.

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):

- **Therapy for Hemophilia A:**
  - Dosage must be individualized based on patient-specific factors- i.e. weight, severity of hemorrhage, presence of inhibitors.
- **Therapy for von Willebrand Disease:**
  - Consult with Hematologist or local rare bleeding disorders clinic.

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 and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

Access: Humate-P® can be given via CVC, PICC, Port-a-Cath®, peripheral IV line.

Reconstitution Supplies:

- Humate-P®, lyophilized in single dose vial
- Diluent (Sterile Diluent for Humate-P®) vial
- Mix2Vial™ filter transfer set

} Contained in box

- Sterile plastic Luer lock syringe (large enough to hold prescribed dose)
- Alcohol swabs

Administration Supplies:

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

Reconstitution: For instructions on using the Mix2vial® for reconstitution go to:
https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-reconst-inst.pdf

Troubleshooting steps in the event of vacuum loss can be found at:
https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-troubleshoot.pdf

Administration:

- Give within 3 hours of reconstitution. **DO NOT** refrigerate after reconstitution.
- **Administration rate:** Maximum 4 mL/min or as requested by the ordering physician or bleeding disorders clinic.
- Dose issued may vary slightly (approx. +/- 10%) from dose ordered.

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.

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: http://www.albertahealthservices.ca/4240.asp

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion. Document start and stop date and time of transfusion.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as 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.
- **Most commonly reported adverse reactions in patients receiving Humate-P® are allergic-anaphylactic reactions (including urticaria, chest tightness, rash, pruritis, edema, and shock).**
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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 OF PRODUCT:

- Stored at 2 - 25°C. **Do not freeze**.

COMMENTS:

Date Effective: 13 Sept 2019
Version: 1.5
Document# PTMGNR00047
Approved By: APL Transfusion Medicine Discipline Council
Reference: Humate-P® Product Monograph, Control #207271
For comments or questions about this document, please contact Transfusion.SafetyTeam@ahs.ca.

LINK to WEBSITE for PRESCRIBING INFORMATION:

http://www.cslbehring.ca