

Hamilton Regional Laboratory Medicine Program (effective at Hamilton Health Sciences, St. Joseph's Healthcare and Associated Health Care Facilities)		
Initial Issue Date: Revision Date:	Administration Guidelines	Section: Laboratory Medicine Sun-Section: <i>Transfusion Medicine</i>
Title: Humate-P (Human)		Document Number:
Approved by: <i>Director, Laboratory Medicine</i> <i>Chair, Regional Transfusion Medicine Committee</i> <i>Head, Transfusion Medicine, HRLMP</i> <i>Manager, Transfusion Medicine, HRLMP</i> <i>Technical Specialist, Transfusion Medicine, HRLMP</i> <i>Chief of Nursing Practice, Hamilton Health Sciences</i> <i>Chief of Nursing Practice, St. Joseph's Healthcare</i>		Page 1 of 4

Purpose: To establish the Indications and Administration of Humate-P.

Scope: Applies to all patient care areas across HHS and St. Joseph's Healthcare.

Definitions: Humate-P is antihemolytic factor/von Willebrand factor complex and is a human, stable, purified, sterile, lyophilized concentrate.

Other Names:	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX	Date Approved:	Pages: 1 of 4
INDICATIONS:			
<ul style="list-style-type: none"> - Adult patients for treatment and prevention of bleeding in hemophilia A - Adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand Disease - Mild and moderate von Willebrand Disease where use of desmopressin is known or suspected to be inadequate 			
DOSAGE:			
<ul style="list-style-type: none"> - Amount to be administered and frequency of application should be oriented to the clinical effectiveness in the individual case - Dosage and duration of the substitution therapy depend on the severity of the disorder of haemostatic function, on the location and extent of the bleeding and on the clinical condition 			
Dosage for Hemophilia A			
<ul style="list-style-type: none"> - General rule, 1 IU Factor VIII activity per Kg body weight will increase circulating Factor VIII level by approximately 2 IU/dl 			

Dosage for von Willebrand’s Disease

- Dosage should be adjusted to the extent and source of bleeding
- General rule, 20 to 40 IU factor VIII:C per kilogram body weight corresponds to 44 - 88 IU vWF:RC of per kilogram body weight
- Administered every 8 to 12 hours

Dosing recommendations for the treatment of von Willebrand Disease

Classification of vWD	Hemorrhage	Dosage (IU vWF:RCof/Kg body weight)
Type 1 <ul style="list-style-type: none"> • Mild, if desmopressin is inappropriate (Baseline vWF:RCof activity typically >30%) 	Major (e.g. sever or refractory epistaxis, GI bleeding, CNS trauma, or traumatic hemorrhage)	Loading dose 40 to 60 IU/Kg, then 40 to 50 IU/Kg every 8 to 12 hours for 3 days to keep the nadir level of vWF:RCof >50%, Then 40 TO 50 IU/Kg daily for a total of up to 7 days of treatment.
<ul style="list-style-type: none"> • Moderate or severe (Baseline vWF:RCof activity typically <30%) 	Minor (e.g. epistaxis, oral bleeding, menorrhagia)	40 to 50 IU/Kg (1 or 2 doses)
	Major (e.g. severe or refractory epistaxis, GI bleeding, CNS trauma, hemarthrosis or traumatic hemorrhage)	Loading dose 50 to 75 IU/Kg, then 40 to 60 IU/Kg every 8 to 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 Factor VIII:C levels should be monitored and maintained according to the guidelines for hemophilia A therapy, Table 4.
Types 2 (all variants) and 3	Minor (clinical indications above) Major (clinical indications above)	40 to 50 IU/Kg (1 or 2 doses) Loading dose of 60 to 80 IU/Kg, then 40 to 60 IU/Kg every 8 to 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 Factor VIII:C levels should be monitored and maintained according to the guidelines for hemophilia A therapy, Table 4.

SUPPLIED:

- **Special Access Product** - must obtain Emergency Drug Release - contact Transfusion Medicine
- 1 vial of dried substance contains a human plasma fraction enriched in blood clotting factor VIII and a von Willebrand factor: ristocetin cofactor activity
- Single dose vials international unit activity of Factor VIII and VWF: RcoF is stated on each carton and vial.
- Stored between 2°C and 8°C; do not freeze
- May also be stored at room temperature for up to 6 months during the expiry period, but not at or above 30°C

RECONSTITUTION AND STABILITY:

- Preparation (including reconstituting, filtering and pooling if required) is preformed in Transfusion Medicine
- See Manufacturer’s information (package insert) for further information
- Reconstituted product should be used immediately

ADMINISTRATION:
– Product must not be further diluted

METHOD	WHO/WHERE	DILUTION	HOW TO ADMINISTER	INFUSION PUMP	PRECAUTIONS AND MONITORING
IV PUSH	RN	No	-Administer filtered product with administration needle - Maximum rate 4 mL/min	No	- Observe and monitor for adverse reactions
MINIBAG/ BURETROL	RN	No	- Administer filtered product using a buretrol or sterile bottle with a vented administration set	Yes	- Observe and monitor for adverse reaction
PRIMARY IV BAG	N/A	N/A	N/A	N/A	N/A
IM or SC	N/A	N/A	N/A	N/A	N/A

COMPATIBILITIES/INCOMPATIBILITIES:
– Interactions with other agents unknown
– Safety of Humate-P in pregnancies has not been established in controlled clinical trials
– Humate-P should not be mixed with other medicinal products

ADVERSE EFFECTS:
– Allergic-anaphylactic reactions and/or rise in temperature may occur in rare cases
– Monitor massive therapy patient for symptoms of hypervolaemia and for haemolytic reactions caused by blood group isoagglutinins that occur in rare cases
– Inhibitors of factor VIII may occur in rare cases

MANAGEMENT OF ADVERSE EFFECTS:
– Notify physician
– Notify Transfusion Medicine
– Mild Reactions - administer corticosteroids and antihistamines
– Severe Reactions (anaphylactic shock) - depending on the severity of the reaction, immediately inject adrenaline (slowly i.v.) plus high doses of corticosteroids (slowly i.v.); volume replacement, oxygen
– Patients known to have a tendency towards allergies should be administered antihistamines and corticosteroids (prophylactically)
– Epinephrine must be available to treat severe symptoms

NOTES:

- Manufactured by Behringwerke AG, Harburg
- Distributed by Canadian Blood Service

Documentation:

Issue transfuse sheets or requisitions with lot numbers must be included in patient's chart.
Written consent for transfusion must be obtained prior to administration.

References:

Product Insert-Antihemophilic Factor/ von Willebrand Factor Complex (Human), Dried, Pasteurized,
Humate-P Aventis Behring GmbH, July 2000

Developed By In Consultation With

Transfusion Medicine Operations Group
Hemophilia Nurse Coordinator

REVIEW DATES:

REVISION DATES: