Humate-P

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Antihemophilic Factor / von Willebrand Factor Complex Product	None

PREPARATION and ADMINISTRATION

Humate-P is a plasma derived factor concentrate, blood consent IS required.

Reconstitution

Diluent: sterile water for injection

See pages 2-4 for reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter prior to administration.

IV Direct	Intermittent Infusion	Continuous Infusion
IV Direct is the recommended route of administration. Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Slowly inject the solution (maximally 4 mL/minute) intravenously with a venipuncture set or with another suitable injection set. If no indwelling IV, use the butterfly and supplies provided in the box.	**IV Bag (large volume pump)** Not Recommended **Syringe (syringe pump)** Not Recommended	**IV Bag (large volume pump)** Not applicable **Syringe (syringe pump)** Not applicable

Requirements and Monitoring

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Document all vitals taken.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Antihemophilic Factor/von Willebrand Factor Complex Humate-P® is indicated for:

- Adult patients for treatment and prevention of bleeding in hemophilia A (classical hemophilia),
- Adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate
- Prevention of excessive bleeding (i.e. bleeding that exceeds the expected blood loss under a given condition) during and after surgery in adult and pediatric patients.

ADVERSE EFFECTS

Humate-P is usually tolerated without reaction. Cases of allergic reaction and rise in temperature have been observed.

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Anaphylactic reactions can occur in rare instances. If allergic/anaphylactic reactions occur, the infusion should be discontinued and appropriate treatment given as required. In some cases, inhibitors of Factor VIII or VWF may occur.

If an AE is suspected: stop the infusion, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume infusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

Check for IWK clinic letter on the SHARE system or for patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system

COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

- None

RECONSTITUTION

Plastic disposable syringes are recommended for withdrawal and administration of Humate-P® solution

1. Before infusion ensure that Humate-P® and diluent vial are at room temperature. Don clean gloves.
2. Remove the Humate-P® and diluent vial flip caps to expose central portions of the rubber stoppers.

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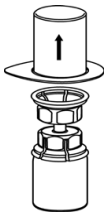
3. Wipe the rubber stoppers with an antiseptic solution such as an alcohol swab and allow to dry prior to opening the Mix2Vial® package.

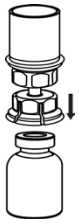
4. Open the Mix2Vial® package by peeling away the lid (Fig. 1).

To maintain sterility, leave the Mix2Vial® in the clear outer packaging. Place the diluent vial on an even surface and hold the vial tight. Grip the Mix2Vial® together with the clear packaging and firmly snap the blue end onto the diluent stopper (Fig. 2).

5. While holding onto the diluent vial, carefully remove the clear outer packaging from the Mix2Vial® set.
6. Make sure that you only pull up the clear outer packaging and not the Mix2Vial® set (Fig. 3).

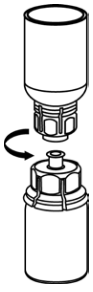


7. With the product vial firmly on a surface, invert the diluent vial with set attached and firmly snap the transparent adapter onto the product vial stopper (Fig. 4). The diluent will automatically transfer into the product vial.



8. With the diluent and product vial still attached, gently swirl the product vial to ensure the product is fully dissolved (Fig. 5). Do not shake vial.

9. With one hand grasp the product-side of the Mix2Vial® set and with the other hand grasp the blue diluent-side of the Mix2Vial® set and unscrew the set into two pieces (Fig. 6).



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10. Draw air into an empty, sterile syringe. While the product vial is upright, screw the syringe to the Mix2Vial® set. Inject air into the product vial. While keeping the syringe plunger pressed, invert the system upside down and draw the concentrate into the syringe by pulling the plunger back slowly (Fig. 7).

11. Now that the concentrate has been transferred into the syringe, firmly grasp the barrel of the syringe (keeping the syringe plunger facing down) and unscrew the syringe from the Mix2Vial® (Fig. 8). Attach the syringe to a venipuncture set.

12. If the same patient is to receive concentrate from more than one vial, the contents of two vials may be drawn into the same syringe through a separate unused Mix2Vial® set before attaching the vein needle.
13. After filtering/withdrawal, inspect for particulate matter prior to administration. Do not use visibly cloudy solutions or solutions still containing flakes or particles after filtration.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration - Policy and Procedure
- Humate-P product monograph. Found at https://www.cslbehring.ca/products/product-list