Kovaltry

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Coagulation Factor VIII Product	None

PREPARATION and ADMINISTRATION

Kovaltry is a recombinant factor VIII product that does not contain human plasma therefore blood consent is not required.

Reconstitution

Diluent: sterile water for injection

See pages 3-5 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 Administer dose over several minutes. Adapt the rate of administration to the response of each individual patient. 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

Indicated for use in adults and children with hemophilia A for:

- Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes
- Control and prevention of episodic bleeding
- Peri-operative management (surgical prophylaxis)

ADVERSE EFFECTS

The most frequently reported adverse reactions in Previously Treated Patients were related to potential hypersensitivity reactions, including headache, pyrexia, pruritus, rash, and abdominal discomfort.

The most frequently reported adverse reactions in Previously Untreated Patients were FVIII inhibitors (low and high titer

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and pyrexia. In addition, erythema or rash were reported.

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.

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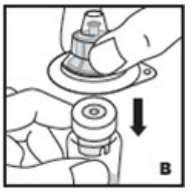
RECONSTITUTION

Always work on a clean surface and done clean gloves before performing the following procedures:

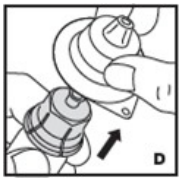
1. Warm both unopened vial and syringe in your hands to a comfortable temperature (do not exceed 37°C). Don clean gloves.
2. Remove protective cap from the vial (A). Aseptically cleanse the rubber stopper with alcohol, being careful not to handle the rubber stopper.

3. Place product vial on a firm, non-skid surface. Peel off the paper cover on the vial adapter plastic housing. Do not remove the adapter from the plastic housing. Holding the adapter housing, place over the product vial and firmly press down (B). The adapter will snap over the vial cap. Do not remove the adapter housing at this step.

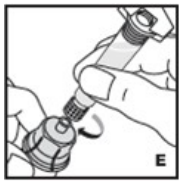


4. Holding the syringe by the barrel, snap the syringe cap off the tip (C).
   Do not touch the syringe tip with your hand or any surface. Set the syringe aside for further use.

5. Now remove and discard the adapter plastic housing (D).



6. Attach the prefilled syringe to the vial adapter thread by turning clockwise (E).

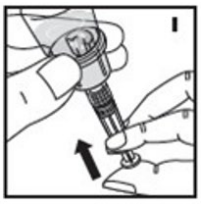


7. Remove the clear plastic plunger rod from the carton. Grasp the plunger rod by the top plate. Avoid touching the sides and threads of the plunger rod. Attach the plunger rod by turning it clockwise into the threaded rubber stopper of the prefilled syringe (F).

8. Inject the diluent slowly by pushing down on the plunger rod.

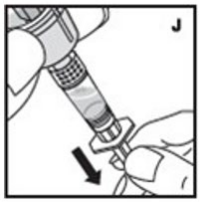
9. Swirl vial gently until all powder on all sides of the vial is dissolved (H). Do not shake vial. Be sure that all powder is completely dissolved. Do not use if solution contains visible particles or is cloudy.

10. Push down on the plunger to push all air back into the vial. Then while holding the plunger down, turn the vial with syringe upside-down (invert) so the vial is now above the syringe (I).

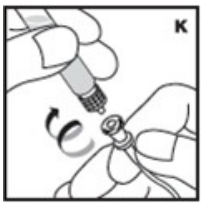


11. Withdraw all the solution into the syringe by pulling the plunger rod back slowly and smoothly (J). Tilt the vial to the side and back to make sure all the solution has been drawn toward the large opening in the rubber stopper and into the syringe.

    Remove as much air as possible before removing the syringe from the vial by slowly and carefully pushing the air back into the vial.



12. Detach the syringe with plunger rod from the vial adapter by turning counter- clockwise. Attach the syringe to the administration set provided and inject intravenously (K).



If the dose requires more than one vial, reconstitute each vial as described above with the diluent syringe provided. Use a larger plastic syringe (not provided) to combine the content of the vials into the syringe.

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Reconstitution of Parenteral Products

Vial Size	Volume of Diluent to be Added to Vial	Approximate Available Volume	Nominal Concentration per mL
250 IU	2.5 mL	2.5 mL	100 unit/mL
500 IU	2.5 mL	2.5 mL	200 unit/mL
1000 IU	2.5 mL	2.5 mL	400 unit/mL
2000 IU	5.0 mL	5.0 mL	400 unit/mL
3000 IU	5.0 mL	5.0 mL	600 unit/mL

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Kovalty product monograph. Found at https://www.bayer.com/en/products/products-from-A-to-Z#K