

TRANSFUSION MEDICINE SERVICES

<b>CLASSIFICATION</b> Recombinant B-domain deleted Coagulation Factor VIII Product Extended Half-life	<b>ALERTS</b> None
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**PREPARATION and ADMINISTRATION**

JIVI is a recombinant 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
<b>IV Direct is the recommended route of administration.</b> Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently  Infuse JIVI intravenously over a period of 1 to 15 minutes, depending on the total volume. Adapt the rate of administration to the response of each individual patient (maximum infusion rate 2.5 mL/min). If no indwelling IV, use the butterfly and supplies provided in the box.	<b>IV Bag (large volume pump)</b>	<b>IV Bag (large volume pump)</b>
	Not Recommended	Not applicable
	<b>Syringe (syringe pump)</b>	<b>Syringe (syringe pump)</b>
	Not Recommended	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 in previously treated adults and adolescents (at or above 12 years of age) with hemophilia A (congenital Factor VIII deficiency) for:

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

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**ADVERSE EFFECTS**

The most frequently reported (5% or over) adverse reactions in clinical trials were headache, cough and pyrexia. Other reported reactions included Abdominal pain, Nausea, Vomiting, Injection site reactions, Pyrexia, Hypersensitivity, Dizziness, Dysgeusia, Headache, Insomnia, Cough, Erythema, Pruritus, Rash and Flushing

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**

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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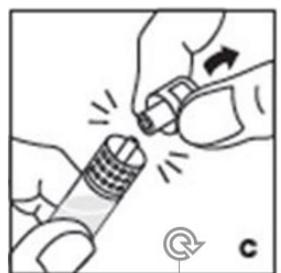
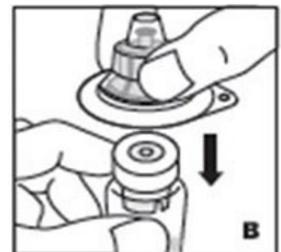
**RECONSTITUTION**

JIVI powder should only be reconstituted with the supplied diluent (2.5 mL Sterile water for Injection) using the prefilled syringe.

The reconstituted product must be filtered prior to administration to remove potential particulate matter in the solution. Filtering is achieved by using the provided Vial Adapter (with a 15 micrometer filter).

If the same patient is to receive more than one bottle, reconstitute each bottle with the diluent syringe provided then combine solutions in a larger syringe (not provided) or empty bag and administer as usual.

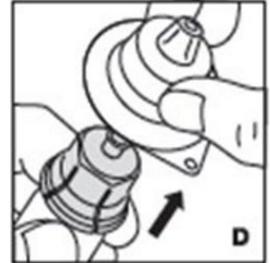
1. Warm both unopened vial and syringe in your hands to a comfortable temperature (do not exceed 37°C, 99°F). Don clean gloves.
2. Remove protective cap from the vial (A). Disinfect the rubber stopper with alcohol, being careful not to handle the rubber stopper.
3. Place product vial on a firm, non-skid 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). To minimize risk of contamination, **do not touch the syringe tip with your hand or any surface**. Set the syringe aside for further use.



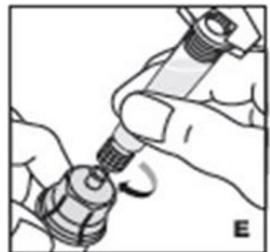
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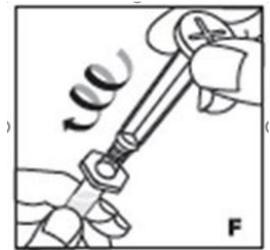
5. Now remove and discard the adapter housing (D).



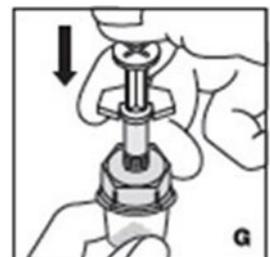
6. Attach the pre-filled syringe to the threaded Vial Adapter by turning clockwise (E).



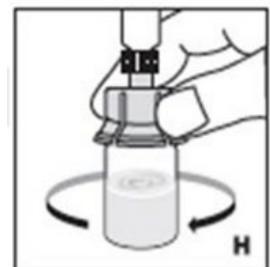
7. Grasp the plunger rod by the top plate and remove from carton. **Avoid touching the sides and threads of the plunger rod.** Immediately attach the plunger rod by turning it firmly clockwise into the threaded syringe rubber stopper (F).



8. Inject the diluent by **slowly** pushing down on the plunger rod (G).



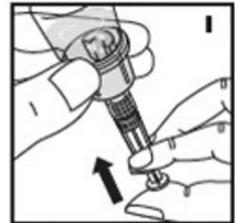
9. Swirl vial gently until all material is dissolved (H). **Do not shake vial.** Be sure that the powder is completely dissolved. **Do not use solutions containing visible particles or that are cloudy.**



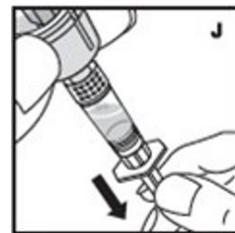
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10. Push down on the plunger to push all air back into the vial. Then while holding the plunger down, turn the vial with syringe upside-down (invert) so the vial is now above the syringe (I).

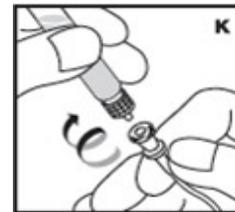


11. Withdraw all the solution into the syringe by pulling the plunger rod back slowly and smoothly (J). Tilt the vial to the side and back to make sure all the solution has been drawn toward the large opening in the rubber stopper and into the syringe.



**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).



**REFERENCES**

- [CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure](#)
- JIVI product monograph. Found at <https://www.bayer.com/en/products/products-from-A-to-Z#>