

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION Recombinant Antihemolytic Factor VIII Product, B-Domain Truncated	ALERTS None
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PREPARATION and ADMINISTRATION

Zonovate is a recombinant VIII product that does not contain plasma therefore a blood consent is not required.

Reconstitution

Diluent: NS for injection

See pages 3–6 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 as reconstituted solution at a rate of 1–2 ml/min. The rate should be determined by the patient’s comfort level. If no indwelling IV, use the butterfly and supplies provided in the box.	IV Bag (large volume pump)	IV Bag (large volume pump)
	Not Recommended	Not applicable
	Syringe (syringe pump)	Syringe (syringe pump)
	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

Zonovate is indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency or classic hemophilia) for:

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Treatment and control of bleeding episodes
- Perioperative management

ADVERSE EFFECTS

The most frequently reported adverse reactions were injection site reactions. Other common reactions included vomiting, pyrexia, muscle hemorrhage, thrombosis in device, cough, rash, flushing. Less common reactions included acute myocardial infarction, sinus tachycardia, fatigue, peripheral swelling, contusion, pain in extremity, musculoskeletal pain/stiffness, burning sensation, dizziness, headache, insomnia, hypertension, hyperemia, lymphedema.

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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.

(Paediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

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

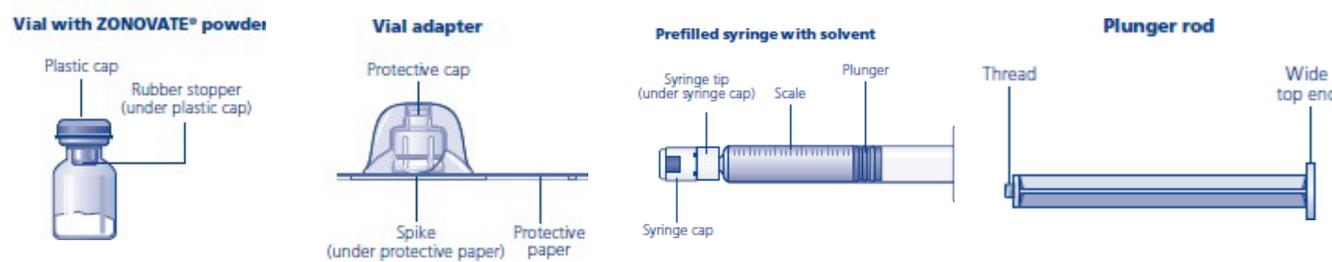
- None

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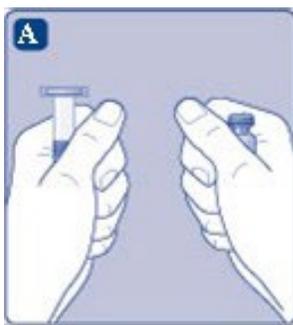
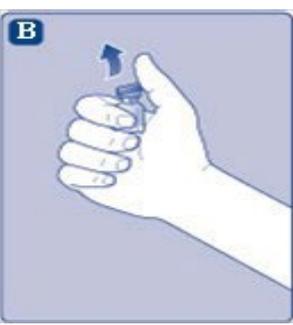
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RECONSTITUTION

Overview

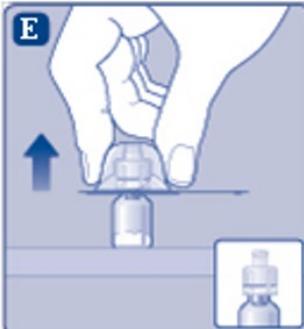
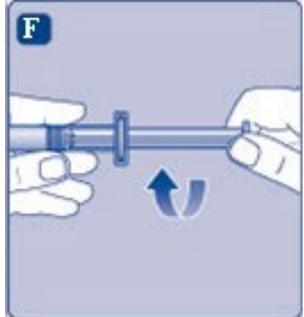


1. Prepare the Vial and Syringe

<p>Step A</p>		<p>Receive the number of ZONOATE® packages you need.</p> <p>Check the expiry date.</p> <p>Check the name, strength and colour of the package, to make sure it contains the correct product.</p> <p>Put on clean gloves</p> <p>Take the vial, the vial adapter and the prefilled syringe out of the carton. Leave the plunger rod untouched in the carton.</p> <p>Bring the vial and the prefilled syringe to room temperature. You can do this by holding them in your hands until they feel as warm as your hands.</p> <p>Do not use any other way to heat the vial and prefilled syringe.</p>
<p>Step B</p>		<p>Remove the plastic cap from the vial. If the plastic cap is loose or missing, do not use the vial.</p> <p>Wipe the rubber stopper with a sterile alcohol swab and allow it to air dry for a few seconds before use to ensure that it is as germ free as possible.</p> <p>Do not touch the rubber stopper with your fingers as this can transfer germs.</p>

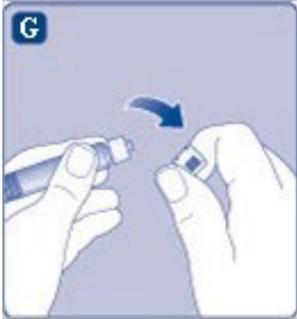
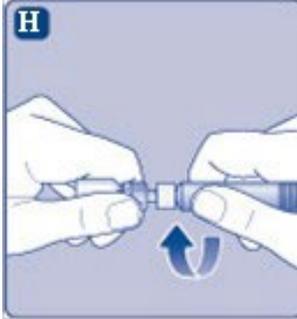
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2. Attach the Vial Adapter		
Step C		<p>Remove the protective paper from the vial adapter.</p> <p>If the protective paper is not fully sealed or if it is broken, do not use the vial adapter.</p> <p>Do not take the vial adapter out of the protective cap with your fingers. If you touch the spike on the vial adapter, germs from your fingers can be transferred.</p>
Step D		<p>Place the vial on a flat and solid surface.</p> <p>Turn over the protective cap, and snap the vial adapter onto the vial.</p> <p>Once attached, do not remove the vial adapter from the vial.</p>
Step E		<p>Lightly squeeze the protective cap with your thumb and index finger as shown.</p> <p>Remove the protective cap from the vial adapter.</p> <p>Do not lift the vial adapter from the vial when removing the protective cap.</p>
3. Attach the Plunger Rod and the Syringe		
Step F		<p>Grasp the plunger rod by the wide top end and take it out of the carton. Do not touch the sides or the thread of the plunger rod. If you touch the sides or the thread, germs from your fingers can be transferred.</p> <p>Immediately connect the plunger rod to the syringe by turning it clockwise into the plunger inside the prefilled syringe until resistance is felt.</p>

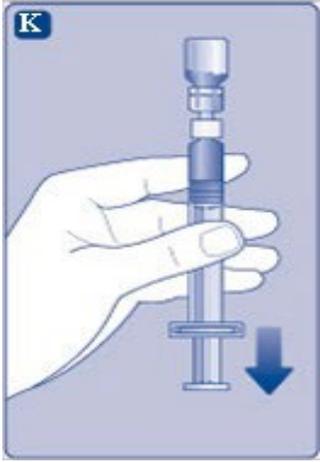
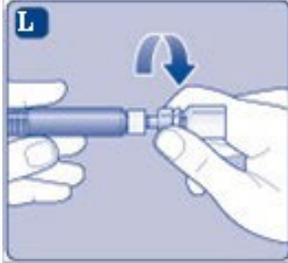
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Step G		<p>Remove the syringe cap from the prefilled syringe by bending it down until the perforation breaks.</p> <p>Do not touch the syringe tip under the syringe cap. If you touch the syringe tip, germs from your fingers can be transferred.</p> <p>If the syringe cap is loose or missing, do not use the prefilled syringe.</p>
Step H		<p>Screw the prefilled syringe securely onto the vial adapter until resistance is felt.</p>
4. Reconstitute the Powder with the Solvent		
Step I		<p>Hold the prefilled syringe slightly tilted with the vial pointing downwards.</p> <p>Push the plunger rod to inject all the solvent into the vial.</p>
Step J		<p>Keep the plunger rod pressed down and swirl the vial gently until all the powder is dissolved.</p> <p>Do not shake the vial as this will cause foaming. Check the reconstituted solution. It must be clear to slightly opalescent (slightly unclear). If you notice visible particles or discoloration, do not use it.</p> <p>If your dose requires more than one vial, repeat step A to J with additional vials, vial adapters and prefilled syringes until you have reached your required dose.</p>

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Step K		<p>Keep the plunger rod pushed completely in. Turn the syringe with the vial upside down.</p> <p>Stop pushing the plunger rod and let it move back on its own while the reconstituted solution fills the syringe.</p> <p>Pull the plunger rod slightly downwards to draw the reconstituted solution into the syringe.</p> <p>If, at any point, there is too much air in the syringe, inject the air back into the vial.</p> <p>While holding the vial upside down, tap the syringe gently to let any air bubbles rise to the top.</p> <p>Push the plunger rod slowly until all air bubbles are gone.</p>
Step L		<p>Unscrew the vial adapter with the vial.</p> <p>Do not touch the syringe tip. If you touch the syringe tip, germs from your fingers can be transferred.</p> <p>Used immediately after it has been reconstituted.</p>

REFERENCES

- [CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure](#)
- Zonovate product monograph. Found at <https://www.novonordisk.com/our-products/our-medicines.html>