Obizur

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Recombinant Antihemophilic Factor VIII Product	None

PREPARATION and ADMINISTRATION

Obizur 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 3-4 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 Administer dose as reconstituted solution at a rate of 1-2 ml/min 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:

Treatment of bleeding episodes in patients with Acquired Hemophilia A (AHA).

ADVERSE EFFECTS

The most frequently reported Adverse Drug Reactions included constipation, diarrhea, hypokalemia, anemia, peripheral edema and a positive anti-porcine inhibitor test result.

If an AE is suspected: stop the insfusion, 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.

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- Resume insfusion 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 insfusion 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.

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
- Reconstituted product can be drawn up with a sterile plastic luer-lock syringe for administration
- 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

Use aseptic technique, a flat work surface during the reconstitution procedure. Don clean gloves.

Powder for Intravenous injection / 500 Units per mL reconstituted with 1 mL of sterile water for injection.

1. Remove cap from the OBIZUR vial to expose the central portion of the rubber stopper and place on a clean surface. Cleanse the rubber stopper with an alcohol swab (not supplied) and allow it to dry prior to use (Figure A).

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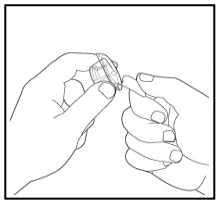
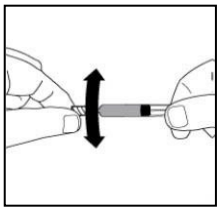
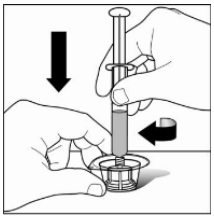
2. Peel back the cover of the vial adapter package (Figure B). Be careful not to touch the luer lock (tip) in the center of the vial adapter. Leave the vial adapter in the package and place it on a clean surface with the luer lock pointing up.



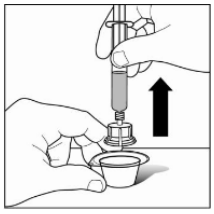
3. Snap off the tamper resistant cap of the pre-filled syringe and place it on a clean surface (Figure C).



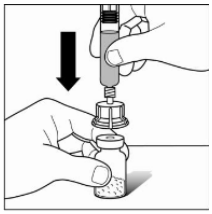
4. Firmly hold the package containing the vial adapter on a clean, flat surface. Connect the pre-filled syringe to the vial adapter by pushing the syringe tip down onto the luer lock in the center of the vial adapter, and screw until the syringe is secured (Figure D).



5. Carefully lift up the combined syringe and vial adapter and remove it from the plastic package (Figure E).

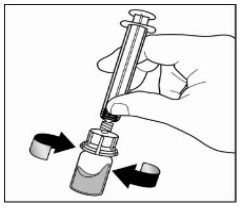


6. With one hand, continue to hold the combined syringe and vial adapter. With the other hand, hold the OBIZUR vial tightly on a clean, flat surface. In a continuous motion, place the vial adapter over the OBIZUR vial; firmly push the filter spike of the vial adapter through the center of the OBIZUR vial's rubber circle until the clear plastic cap snaps onto the vial (Figure F).



Note: Some of the liquid in the pre-filled syringe may automatically transfer into the OBIZUR vial. **Push the plunger down** to complete the transfer of all liquid from the syringe into the OBIZUR vial.

7. With the syringe and the vial still attached, gently swirl (in a circular motion) until the product is fully dissolved /reconstituted (Figure G).



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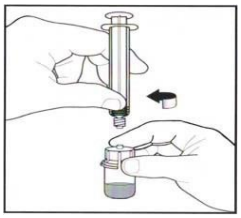
8. With one hand hold the vial and vial adapter, and with the other hand firmly grasp the barrel of the pre-filled syringe and unscrew the syringe from the vial adapter (Figure H).



Administration

Once all vials have been reconstituted, using a new large sterile syringe of the appropriate size for the volume (not supplied), pull back the plunger and admit air into the syringe.

Connect the large syringe to the vial adapter by pushing the syringe tip down onto the luer lock in the center of the vial adapter, and screw until the syringe is secured.

Withdraw the reconstituted OBIZUR into the syringe (Figure I).

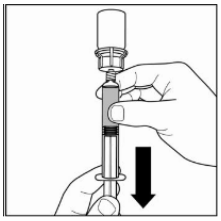


Figure I

Unscrew the large syringe and repeat this process for all reconstituted vials of OBIZUR until total volume to be administered is reached.

Administer the total volume as a slow bolus infusion at a rate of **1-2 mL per minute**.

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration - Policy and Procedure
- Obizur product monograph. Found at https://www.takeda.com/en-ca/what-we-do/our-medicines/