ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Obizur®

APPLICABILITY: This document applies to all APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *recombinant Factor VIII, antihemophilic factor, porcine sequence* ***Company:*** *Takeda Canada* ***Class:*** *Manufactured recombinant product*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	Yes	No	No	N/A

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- Obizur® is a sterile nonpyrogenic lyophilized concentrate of recombinant factor VIII, porcine sequence.
- Supplied in 500 unit single-dose vials. Actual porcine factor VIII potency in units is stated on the vial.
- Reconstituted solution is clear and colourless.
- Also contains sodium chloride, calcium chloride, polysorbate 80, tris, tri-sodium citrate, and sucrose
- **Latex-free**

AVAILABILITY:

- Supplied by Canadian Blood Services.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Treatment of bleeding episodes in patients with acquired hemophilia A

CONTRAINDICATIONS:

- History of life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster and porcine proteins.
- Congenital hemophilia A with inhibitors

WARNINGS:

- Development of activity-neutralizing antibodies has been detected in patients receiving Factor VIII-containing products. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, an assay that measures factor VIII inhibitor concentration should be performed.
- Safety and efficacy has not been established in patients with a baseline anti-porcine factor VIII inhibitor titre of greater than 20 BU.
- The safety and efficacy of OBIZUR have not been established in pediatric patients.
- High and sustained factor VIII activity in blood may predispose to thromboembolic events. Those with pre-existing cardiovascular disease and the elderly are at particular risk. Plasma levels of factor VIII should not exceed 200% of normal.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MHRP).
- Recommended Dosing and Frequency Guidance for Treatment of Bleeding Episodes with OBIZUR

Type of Bleeding Episode	Dosage Necessary to Maintain the Therapeutic Plasma Level	Target trough Factor VIII Blood Activity (% of Normal or Units per dL)	
		For Bleeding	For Healing
Mild superficial extremity intramuscular and joint	▪ 200 units per kg initial dose ▪ Subsequent dose to be administered every 4 to 12 hours based on clinical response and measured factor VIII levels	50-100%	50-100%
Moderate to severe intramuscular bleeding Retroperitoneal, gastrointestinal, intracranial	▪ 200 units per kg initial dose ▪ Subsequent dose to be administered every 4 to 12 hours based on clinical response and measured factor VIII levels	100-200%	50-100%

- **Treatment for bleeding episodes and surgical procedures:**
  - Refer to patient's care plan or Factor First card, if available
  - If neither are available, consult with bleeding disorders clinic or transfusion medicine physician.
- Dosage, frequency, and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding, presence of inhibitors, Factor VIII level desired, and the patient's clinical condition.

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per nursing protocol.

Access: Product can be given via CVC, PICC, or peripheral IV line

Reconstitution Supplies:

- Obizur® Product (lyophilized powder)
- 1 mL sterile water for injection (prefilled luer-lock syringe included with product)
- Vial adapter with filter (included with product)
- Alcohol swabs (not included with product)

Administration Supplies:

- Infusion set (not included with product)
- Sterile plastic luer lock syringe, large enough to contain dose**
- If transferring to a mini-bag: sterile empty minibag, large enough to contain the dose

* **Note:** Obizur can be administered through an administration set without a filter since filtering is achieved through reconstitution with the vial adapter.

** **Note:** The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile plastic syringe with a standard luer-lock connector. Ensure the vial adapter is used when withdrawing the solution from the vial into the syringe.

Reconstitution:

- See Obizur reconstitution instructions.

Administration:

- Do not use solutions that are cloudy, have deposits, or are not colourless
- Give immediately after reconstitution (within 3 hours).
- Do Not refrigerate after reconstitution
- Do Not mix with other drugs or IV solutions.
- Flush with 0.9% sodium chloride for injection

  - Option 1: Direct IV
    - Recommended administration as a slow direct IV at a rate of 1 - 2 mL per minute.
    - Do not administer as an intravenous push or bolus
  - Option 2: Transfer to Minibag:
    - Transfer reconstituted Obizur® into a sterile empty minibag.
    - Prime the line with Obizur®.
    - Infuse the prescribed amount at the appropriate rate.
    - Flush using normal saline.
  - Option 3: Syringe pump: (Microbore tubing required).

Administration Rate:

- Administration rate should be specified by the MRHP after patient assessment.
- Recommended rate 1-2 mL per minute

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- Provide patient notification documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

Adverse Events

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- The most commonly reported adverse reactions in patients receiving Obizur include constipation, diarrhea, hypokalemia, anemia, peripheral edema and a positive antiporcine inhibitor test result.

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→ **Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→ **Action** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- Stored at 2-8°C.
- **Do not freeze**.
- Keep protected from light.
- Do not use expired product

Contact Information

Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

Obizur® Product Monograph (Revised March 9, 2023). obizur-pm-en.pdf (takeda.com)

Association of Hemophilia Clinic Directors of Canada Recommendations for Obizur