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:*** *Shire Pharma Canada* ***Class:*** *Manufactured recombinant product*

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

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

DESCRIPTION OF PRODUCT:

- Obizur® is a sterile 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 dehydrate, 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.

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).
- **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 written (signed) consent has been obtained and documented prior to requesting blood component 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**

* **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.
- **Administration Rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended administration as a slow bolus infusion at a rate of 1-2 mL per minute, or attach a large syringe to a syringe pump set at 1-2 mL per minute
  - Do not administer as an intravenous push or bolus
- Flush with 0.9% sodium chloride for injection

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:

- 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.
- 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 OF PRODUCT:

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

COMMENTS:

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

REFERENCES:

Obizur® Product Monograph. Available from www.takeda.com

Association of Hemophilia Clinic Directors of Canada Recommendations for Obizur

Canadian Blood Services Customer Letter CL2018-07. Available from www.blood.ca