ALBERTA PRECISION LABORATORIES
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Esperoct®

Factor VIII Concentrate (Recombinant)

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 ***Company:*** *Novo Nordisk* ***Class:*** *Manufactured recombinant factor, extended half-life*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	No	No	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:

- Esperoct® is a purified, lyophilized concentrate of B-domain truncated, PEGylated, recombinant human factor VIII.
- Pathogen inactivation/removal steps include chromatography, detergent treatment, and nanofiltration.
- Product is a white to off-white lyophilized powder.
- Reconstituted solution is clear and colourless.
- Available in 500 IU, 1000 IU, 1500IU, 2000IU, and 3000IU single use glass vials.
- Vials are reconstituted with 4mL of 0.9% sodium chloride.
- Also contains sodium chloride, L-Histidine, Sucrose, Polysorbate 80, L-methionine, Calcium chloride dihydrate.
- Latex free.

AVAILABILITY:

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

INDICATIONS:

- Adults and children with hemophilia A (congenital Factor VIII Deficiency) for:
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
  - On-demand treatment and control of bleeding episodes
  - Perioperative management (surgical prophylaxis).

CONTRAINDICATIONS:

- Patients with known anaphylactic or severe systemic reactions to the product or any ingredient in the formulation or component of the container, including hamster proteins.
- Patients with von Willebrand disease (does not contain von Willebrand Factor).

WARNINGS:

- The formation of neutralizing antibodies (inhibitors) is a known complication in the management of individuals with Hemophilia A. All patients treated with coagulation FVIII should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests.
- The product contains traces of hamster proteins, which in some patients may cause allergic reactions.
- In some previously untreated pediatric patients, a decreased FVIII recovery has been observed in the absence of detectable FVIII inhibitors. Close monitoring of previously untreated pediatric patients including monitoring of the patient's clinical status and post dose FVIII activity is recommended until the incremental recovery is normalized.

DOSE: (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MRHP) only after consult with Hematologist or bleeding disorders clinic.
- Refer to patient's care plan or Factor First card, if available
- Dosage 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 and individual clinical response.
- One IU of FVIII activity is equivalent to that quantity of FVIII in one mL of normal human plasma.
- The calculation of the required dose of FVIII is based on the empirical finding that 1 IU FVIII per kg body weight raises the plasma FVIII activity by 2 IU/dL.

Manufacturer Recommended Dosing:

Indication	Situation	Target (% of normal FVIII)	Recommended Dosing	
			Pediatric (under 12 years)	Adults and Adolescents (12 years and older)
Prophylaxis	Routine	N/A	60IU/kg (50-75IU) per kg Twice weekly	50 IU per kg Every 4 days
On-demand	Minor Bleeding	20-40	40 IU per kg Administered once	65 IU per kg Administered once
	Moderate Bleeding	30-60	40 IU per kg Repeat after 24 hrs if required	65 IU per kg Repeat after 24 hrs if required
	Major Bleeding	60-100	50 IU per kg Repeat every 24 hrs if required	65 IU per kg Repeat every 24 hrs if required
Perioperative management	Minor Surgery	30-60	65 IU per kg Repeat after 24 hrs if required	50 IU per kg Repeat after 24 hrs if required
	Major Surgery	80-100	65 IU per kg First dose pre-operatively Repeat every 24 hrs for first week Repeat every 48 hrs until healing achieved	50 IU per kg First dose pre-operatively Repeat every 24 hrs for first week Repeat every 48 hrs until healing achieved
Dosage Required (IU) = Body Weight (kg) × Desired Factor VIII Increase (IU/dL or % normal) × 0.5 (IU/kg per IU/dL)				

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required (ie. Factor VIII)
- Ensure any ordered premedications have been given (antihistamines, antipyretics prn).
- Perform pre-transfusion checks per AHS Transfusion of Blood Components and Blood Products Policy.
- Report any new onset acute illness to the authorized prescriber prior to commencing infusion.

Access: Esperoct® can be given via peripheral or central venous access site.

Reconstitution Supplies:

- Esperoct® Product (lyophilized powder)
- 0.9% sodium chloride (prefilled syringe* included with product)
- Vial adapter (included with product)
- Plunger rod (included with product)
- Alcohol swabs (not included with product)

Reconstitution:

- Bring the product and diluent to room temperature prior to reconstitution.
- Refer to Prefilled Syringe with Vial Adapter Reconstitution Instructions.
- Esperoct® should be visually inspected for particulate matter and discoloration prior to administration. Do not use solutions that are visibly cloudy or have deposits.

Compatible IV Solutions:

- Do not mix with other medicinal products or solutions.
- Normal saline can be used to flush the line.

ADMINISTRATION cont'd:

Administration Supplies:

- Alcohol swabs
- Infusion set (not included with product)
- Sterile plastic luer lock syringe, large enough to contain dose*

* **Note:** The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needleless 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.

Administration:

- Esperoct® must be administered within 4 hours after reconstitution.
- If product cannot be administered immediately, refer to storage and stability section below.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended direct IV infusion over several (5-10) minutes, or as requested by MRHP or bleeding disorder clinic.

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 common adverse events associated with Esperoct® in clinical trials were rash, erythema, pruritus, and injection site reactions.

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

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post

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: http://www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed per the AHS Transfusion of Blood Components and Blood Products Policy
- Patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification documentation where required.

STORAGE & STABILITY:

- Store at 2-8°C until expiry.
- The lyophilized powder may be stored at higher temperatures for a limited amount of time. Once stored above refrigerated temperature, do not return the product to refrigerated storage.
  - Room temperature (up to 30°C) for a single period up to 12 months.
  - 30-40°C for a single period up to 3 months.
- If the reconstituted solution cannot be used immediately, it may be stored in the **vial** for a limited amount of time. Do not store in syringes.
  - 2-8°C for up to 24 hours.
  - Room temperature (below 30°C) for up to 4 hours.
  - 30-40°C for up to 2 hours.
- Protect from light.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments please contact Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

NovoNordisk Canada Inc. 6 May 2020, Esperoct® Product Monograph. Submission Control No: 235688. [Accessed 2022Mar22] https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/esperoct-product-monograph.pdf