ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

PrKOVALTRY™

APPLICABILITY: This document applies to 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: Bayer*** ***Class:*** *Manufactured anti-hemophilic recombinant factor*

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

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**

DESCRIPTION OF PRODUCT:

- PrKOVALTRY™ is a sterile, lyophilized concentrate of recombinant factor VIII manufactured using recombinant DNA technology.
- Each PrKOVALTRY™ vial contains the labeled amount of recombinant antihemophilic factor activity expressed in IU per vial
- Dispensed in 250 IU, 500 IU, 1000 IU, 2000 IU, and 3000 IU single use glass vials
- Contains sucrose, histidine, glycine, sodium chloride, calcium chloride and Polysorbate 80
- **Latex-free**

AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site

INDICATIONS FOR USE:

- For adults and children with hemophilia A for:
  - Routine prophylaxis to reduce the frequency of bleeding episodes
  - Control and prevention of bleeding episodes
  - Perioperative management (surgical prophylaxis)

CONTRAINDICATIONS:

- History of life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins
- Patients with von Willebrand disease (does not contain von Willebrand Factor)

WARNINGS:

- Development of activity-neutralizing antibodies (inhibitors) 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
- Patients may develop hypersensitivity to mouse or hamster protein (present in trace amounts in the product)

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MHRP) **only** after consult with Hematologist or bleeding disorders clinic.
- 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.
- Dose issued may slightly vary (+/- 10%) from dose ordered (based on vial sizes)
- **Prophylaxis in pediatric patients (≤ 12 years old):**
  - Manufacturer recommended dose = 20-50 IU/kg twice weekly, three times weekly or every other day depending on individual requirements
- **Prophylaxis in Adults and Adolescents (> 12 years old):**
  - Manufacturer recommended dose = 20-40 IU/kg two or three times per week
- **Prophylaxis:** Refer to package insert supplied with product
- **On-demand treatment:**
  - 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.

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

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

Reconstitution Supplies:

- Kovaltry® Product (lyophilized powder)
- 2.5 or 5.0 mL sterile water for injection (prefilled syringe included with product)
- Vial adapter (included with product)
- Alcohol swabs (not included with product)

Administration Supplies:

- IV administration set (included with product)*
- Sterile plastic luer lock syringe, large enough to contain dose **

* **Note:** Kovaltry 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:

- Refer to Bayer Vial Adapter reconstitution instructions. https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-bayer-vial-adapter-reconst.pdf
- **Do Not** refrigerate after reconstitution

Administration:

- Kovaltry® must be administered within 3 hours after reconstitution.
- It is recommended to use the administration set provided to minimize losses of product due to adsorption and volume retention.
- Kovaltry® should not be mixed with other medicinal products or solutions
- **Administration rate:**
  - Administration rate should be specified by the MHRP after patient assessment.
  - Recommend direct IV administration over a period of bolus injection usually over several (5-10) minutes, determined by patient comfort, or as requested by MHRP 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.
- Allergic-type hypersensitivity reactions including anaphylaxis have been reported and have manifested as pruritis, rash, urticaria, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.
- **The most common adverse reactions observed are related to potential hypersensitivity reactions including: headache, pyrexia, pruritis, rash and abdominal discomfort.**

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:

- 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.

STORAGE & STABILITY OF PRODUCT:

- Store at 2-8°C
- The lyophilized powder may be stored at up to 25°C for up to 12 months, or until the expiry date on the vial (whichever is shorter). Ensure the date the product is removed from the refrigerator is recorded. Once stored at room temperature, do not return the product to refrigerated storage.
- **Do not freeze.**
- Protect from light

COMMENTS:

Date Effective: 2 Sept 2020
Version: 1.31
Approved By: APL Transfusion Medicine Discipline Council
Document Number: TM40-01.02.011
For questions or comments about this document, please contact Transfusion.SafetyTeam@albertaprecisionlabs.ca

REFERENCES

KOVALTRY® Product Monograph. Available from www.bayer.ca