ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Corifact®
Factor XIII Concentrate (human)

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:*** Factor XIII (human) ***Company:*** *Bayer* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	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.**

**** Direct IV Administration of Blood Products may be performed by professionals per the Transfusion of Blood Components and Products Learning Module. Not to be confused with medication administration.**

DESCRIPTION:

- Corifact® is a sterile, lyophilized concentrate of recombinant factor XIII manufactured from human plasma.
- Viral reduction/inactivation steps include precipitation/adsorption, ion exchange chromatography, heat treatment, and nanofiltration.
- Product is a white lyophilized powder.
- Reconstituted solution is colorless to slightly yellowish, slightly opalescent, and free from visible particles.
- Available in in 250 IU and 1250 IU single use glass vials**.**
- Vials are reconstituted with sterile water for injection (4mL and 20mL respectively).
- Also contains human albumin, glucose monohydrate and sodium chloride.
- Preservative-free.
- Latex-free.

AVAILABILITY

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

INDICATIONS FOR USE:

- Routine prophylactic treatment and peri-operative management of surgical bleeding in adults and pediatric patients with congenital Factor XIII deficiency.

CONTRAINDICATIONS:

- Patients with known anaphylactic or severe systemic reactions to human plasma-derived products or any ingredient in the formulation or components of the container.

WARNINGS:

- Thromboembolic complications have been reported in patients receiving Corifact®. Monitor patients with known risk factors for thrombotic events. Consider baseline assessment of blood viscosity for those at risk for hyperviscosity.
- Development of inhibitory antibodies against FXIII has been detected in patients receiving Corifact®. Monitor patients for possible development of inhibitory antibodies. Presence of inhibitory antibodies may manifest as an inadequate response to treatment.

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.
- Dosing regimen should be individualized based on body weight, laboratory values, and the patient's clinical condition.
- The method of administration in children and adolescents is based on body weight and is therefore generally based on the same guidelines as for adults.
- Adjustments to dosing may be different than these recommendations and is to be individualized based on FXIII activity levels and the patient's clinical condition. Monitor closely all patients during and after surgery. In the case of major surgery and severe hemorrhage, the aim is to obtain near normal values (healthy persons: 70% - 140%).
- **Routine Prophylaxis:**
  - Recommended dose: 40 IU per kg body weight.
  - Dosing is to be guided by the most recent trough FXIII activity level, with dosing every 28 days (4 weeks) to maintain a trough FXIII activity level of approximately 5% to 20%.
- **Prophylaxis prior to surgery:** After the patient's last routine prophylactic dose, if a surgery is scheduled:
  - Between 21 and 28 days later – Administer the patient's full prophylaxis dose immediately prior to surgery and the next prophylactic dose should be given 28 days later.
  - Between 8 and 21 days later – An additional partial or full dose may be administered prior to surgery. The dose should be guided by the patient's FXIII activity levels and clinical condition and adjusted based upon the half-life of Corifact®.
  - Within 7 days of last dose – Additional dosing may not be needed.

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: Peripheral or central venous access site.

Reconstitution Supplies:

- Corifact® product (lyophilized powder)
- Solvent (Sterile Water for Injection, included with product)
- Mix2Vial filter transfer set (included with product)
- Alcohol swabs
- Sterile plastic Luer lock syringe (large enough to hold prescribed dose)

Reconstitution:

- Bring Corifact® to room temperature before reconstitution.
- See *Mix2Vial Reconstitution Instructions.*
- Corifact® should be visually inspected for particulate matter and discoloration prior to administration. Do not use visibly cloudy solutions or solutions still containing flakes or particles after filtration.
- Do not refrigerate after reconstitution.

Compatible IV Solutions:

- Corifact® should not be mixed with other medicinal products or solutions.
- Normal saline can be used to flush the line.

Administration Supplies:

- **Direct IV administration:**
  - Sterile plastic Luer lock syringe (large enough to hold prescribed dose)
- **For IV infusion:**
  - IV administration set
  - IV pump

* Note: Corifact® can be administered through an administration set without a filter since filtering is achieved through reconstitution with the Mix2Vial device.

Administration:

- Administer within 3 hours after reconstitution.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Maximum rate is 4 mL/min or as requested by the ordering physician or bleeding disorders clinic.

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

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Blood Products Policy.
- Start and stop time of infusion and assessment of 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 of transfusion documentation where required.

Laboratory Monitoring

- Monitoring patient's trough FXIII activity level is recommended during treatment with Corifact®
- If breakthrough bleeding occurs, or if expected peak plasma FXIII activity levels are not attained perform an investigation to determine the presence of FXIII inhibitory antibodies.

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 reactions observed are joint inflammation, hematoma, arthralgia, hypersensitivity, rash, pruritis, erythema, headache, pyrexia, elevated thrombin-antithrombin levels and increased blood lactate dehydrogenase.
- The most serious adverse reactions observed are hypersensitivity, acute ischemia, and neutralizing antibodies against FXIII.

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:

- Store at 2-8°C until expiry (up to 36 months from date of manufacture).
- Protect from light.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council

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

REFERENCES:

CSL Behring Canada, Inc. Corifact® Product Monograph. Jan 2018. Control #211153. [Accessed 12Nov21]. https://labeling.cslbehring.ca/PM/CA/Corifact/EN/Corifact-Product-Monograph.pdf

PS-59 AHS Transfusion of Blood Components and Blood Products Policy.