Alberta Health Services

This document applies to all Covenant and AHS sites

Corifact™

Class: *Manufactured factor concentrate*

OTHER NAMES: FXIII, Factor XIII Concentrate, Human

Company: Bayer

	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.**

**** 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:

- Corifact™ is a sterile, lyophilized concentrate of recombinant factor XIII manufactured
- It is derived from human plasma, presented as a white lyophilized powder to be reconstituted with Sterile Water for Injection (included in packaging)
- Dispensed in 250 IU and 1250 IU single use glass vials
- Contains human albumin, glucose monohydrate and sodium chloride
- **Latex-free**

AVAILABILITY:

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

INDICATIONS FOR USE:

- Corifact™ is indicated for 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 to any components in Corifact™.

WARNINGS:

- Corifact™ (Factor XIII Concentrate, Human) is made from human plasma. For medicinal products prepared from human plasma the possibility of transmitting infective agents cannot be totally excluded. This applies to unknown or emerging viruses and other pathogens.
- Taking into consideration the efficacy of donation screening and the virus inactivation/removal capacity of the manufacturing process it can be concluded that all measures taken during the production of Corifact™ are effective for enveloped viruses such as HIV, HBV and HCV and for the non-enveloped viruses HAV and Parvovirus B19. Appropriate vaccination (hepatitis A and B) should be generally considered for patients in regular/repeated receipt of human plasma-derived products.

DOSE (Refer to Product Insert):

- 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.
- **Routine Prophylaxis:**
  - 40 International Units (units)a 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.
- 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 haemorrhages the aim is to obtain near normal values (healthy persons: 70% - 140%).

**** Consult with Hematologist or bleeding disorders clinic ****

ADMINISTRATION:

Ensure written (signed) patient consent has been obtained prior to requesting blood product 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, Port-a-Cath®, or peripheral IV line

Reconstitution Supplies:

- Reconstitution device: Mix2Vial™ filtered transfer set
- Vial with diluent (4 mL or 20 mL sterile water for injection)

} Contained in box

Administration Supplies:

- **For direct IV administration:**
  - Sterile plastic Luer lock syringe (large enough to hold prescribed dose)
  - Filtered butterfly set (20 micron injection filter required)
- **For IV infusion:**
  - IV administration set and IV pump

Reconstitution:

Refer to reconstitution instructions using Mix2Vial™ steps at;
https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-reconst-inst.pdf

Mix2Vial™ trouble shooting instructions can be found at;
https://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-troubleshoot.pdf

Administration:

- Give immediately after reconstitution (within 3 hours)
- **DO NOT** refrigerate after reconstitution
- **Administration rate:** not to exceed 4 mL per minute

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	→	**Action:** **STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** during 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, refer to the following link:
http://www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products procedure
- Recipients of blood products are notified in writing of the transfusion as per the AHS Transfusion of Blood Components and Products Policy.

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C . **Do not freeze**.
- Product is viable for up to 36 months from date of manufacture (expiry date on the vial)
- Protect from light. Do not freeze.

COMMENTS:

Date Effective: 13 Sept 2019
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For questions or comments about this document, please contact Transfusion.SafetyTeam@ahs.ca

REFERENCES

Product Monograph SCN 186659
http://www.cslbehring.ca/