



# Coagadex®

<b>APPLICABILITY:</b> 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.			<b>Other Names:</b> Factor X <b>Company:</b> BPL Bio Products Laboratory Ltd <b>Class:</b> Manufactured blood product, derived from human plasma			
In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.						
	<b>INTRAVENOUS</b>			<b>OTHER</b>		
<b>ROUTES</b>	<b>DIRECT IV</b>	<b>IV Infusion</b>	<b>Continuous Infusion</b>	<b>SC</b>	<b>IM</b>	<b>OTHER</b>
<b>Acceptable Routes*</b>	Yes**	Yes	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.						
<b>DESCRIPTION:</b>						
<ul style="list-style-type: none"> <li>Coagadex® (Factor X [human]) is prepared from large pools of human plasma.</li> <li>Viral inactivation and/or removal processes include: solvent detergent treatment, nanofiltration and dry-heat treatment.</li> <li>Available in 250 IU or 500 IU single-dose vials of sterile, preservative-free lyophilized powder</li> <li>After reconstitution with the full volume of supplied diluent (2.5 mL or 5 mL sterile water for injection), human Factor X concentration is 100 IU/mL</li> <li>Also contains chloride, phosphate, citrate and sucrose as well as up to 400 mmol/L of sodium. This should be taken into consideration by patients on a controlled sodium diet.</li> </ul>						
<b>AVAILABILITY</b>						
<ul style="list-style-type: none"> <li>Coagadex® is an unlicensed product in Canada. Patient-specific requests must be approved by Health Canada's Special Access Programme (SAP). Authorized prescriber must contact Transfusion Medicine physician.</li> </ul>						
<b>INDICATIONS FOR USE:</b>						
<ul style="list-style-type: none"> <li>Indicated in adults and children with hereditary Factor X deficiency for: <ul style="list-style-type: none"> <li>Routine prophylaxis to reduce the frequency of bleeding episodes</li> <li>On-demand treatment and control of bleeding episodes</li> <li>Perioperative management of bleeding in patients with mild, moderate, and severe hereditary Factor X deficiency</li> </ul> </li> </ul>						
<b>CONTRAINDICATIONS:</b>						
<ul style="list-style-type: none"> <li>Patients who are hypersensitive (allergic) to this drug or any ingredient in the formulation or container (see product monograph for complete listing).</li> </ul>						
<b>WARNINGS:</b>						
<ul style="list-style-type: none"> <li>Hypersensitivity reactions, including anaphylaxis, are possible.</li> <li>Development of neutralizing antibodies (inhibitors) may occur. If expected plasma Factor X activity levels are not attained, or if bleeding is not controlled with an appropriate dose, perform an assay that measures Factor X inhibitor concentration.</li> <li>Certain anticoagulants including those blocking a clotting factor (Factor Xa) should not be used in patients with a Factor X deficiency receiving Coagadex® due to a risk of blood clots.</li> </ul>						

**DOSE:**

- Dose and duration of the treatment depend on the severity of the Factor X deficiency, location and extent of the bleeding, the patient's age and the patient's clinical condition.
- Base the dose and frequency on the individual clinical response. Do not administer more than 60 IU/kg daily.
- If necessary, consult with TM Physician / Pathologist on call for bleeding patients.

**Pediatrics less than 12 years of age**

Clinical Indication	Factor X Dose	Further Management
Prophylaxis of bleeding episodes	40 IU/kg twice weekly	Recommended that trough blood levels of Factor X should be monitored at intervals, especially in the first weeks of therapy or after dosages changes. Adjust dosage regimen to clinical response and trough levels of Factor X of at least 0.05 IU/mL. Do not exceed a peak level of 1.20 IU/mL.
On-demand treatment and control of bleeding episodes	30 IU/kg	Infuse Factor X when the first sign of bleeding occurs. Repeat at intervals of 24 hours until the bleed stops
Perioperative management of bleeding	Use a factor of 0.6 to calculate the required dose <sup>1</sup>	Measure post-infusion plasma Factor X levels for each patient before and after surgery to ensure that hemostatic levels are obtained and maintained. Pre-surgery: calculate the dose of Coagadex® to raise plasma Factor X levels to 0.70-0.90 IU/mL Post-surgery: Repeat dose as necessary to maintain plasma Factor X levels at a minimum of 0.50 IU/mL until the patient is no longer at risk of bleeding due to surgery
<sup>1</sup> Dose (IU) = Body Weight (kg) x Desired Factor X increase (IU/dL or % of normal) x 0.6		

**Pediatrics 12 years of age or older and Adults**

Clinical Indication	Factor X Dose	Further Management
Prophylaxis of bleeding episodes	25 IU/kg twice weekly	Recommended that trough blood levels of Factor X should be monitored at intervals, especially in the first weeks of therapy or after dosages changes. Adjust dosage regimen to clinical response and trough levels of Factor X of at least 0.05 IU/mL. Do not exceed a peak level of 1.20 IU/mL.
On-demand treatment and control of bleeding episodes	25 IU/kg	Infuse Factor X when the first sign of bleeding occurs. Repeat at intervals of 24 hours until the bleed stops
Perioperative management of bleeding	Use a factor of 0.5 to calculate the required dose <sup>2</sup>	Measure post-infusion plasma Factor X levels for each patient before and after surgery to ensure that hemostatic levels are obtained and maintained. Pre-surgery: calculate the dose of Coagadex® to raise plasma Factor X levels to 0.70-0.90 IU/mL Post-surgery: Repeat dose as necessary to maintain plasma Factor X levels at a minimum of 0.50 IU/mL until the patient is no longer at risk of bleeding due to surgery
<sup>2</sup> Dose (IU) = Body Weight (kg) x Desired Factor X increase (IU/dL or % of normal) x 0.5		

**ADMINISTRATION:**

***Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) from lab/transfusion service where possible.***

**Pre-Infusion:**

- Ensure recent patient weight is on file and pertinent labs are ordered if required and time allows.
- Perform pre-transfusion checks per [AHS Transfusion Policy and Procedure](#).

**Access:** Peripheral or central venous access site.

**Reconstitution Supplies:**

- Vial of Coagadex® lyophilized powder
- Sterile Water for Injection, USP (included with product)
- Mix2Vial filter transfer device (included with product)
- Alcohol swabs
- Sterile plastic Luer lock syringe (large enough to hold prescribed dose)

**Reconstitution:**

- Bring Coagadex® and Sterile Water to room temperature before reconstitution.
- See [Mix2Vial Reconstitution Instructions](#).
- Coagadex® 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:**

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

**Administration:**

- Administer within 1 hour after reconstitution.
- Administration rate should be specified by the MRHP after patient assessment.
- Maximum rate is 20 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 to a transfusion reaction see [Transfusion Reactions | Alberta Health Services](#). Notify the transfusion service as soon as possible that an adverse reaction has occurred.

**Documentation:**

- Ensure documentation is completed as per the [AHS Transfusion of Blood Components and 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 FX activity level is recommended during treatment with Coagadex®
- If breakthrough bleeding occurs, or if expected peak plasma FX activity levels are not attained, perform an investigation to determine the presence of FX inhibitory antibodies.

## POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

### Adverse Events

- 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 hypersensitivity (allergic reactions), infusion site erythema and / or pain, fatigue, and back pain.
- The most serious adverse reactions observed are hypersensitivity and neutralizing antibodies against FX.

#### 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°C - 30°C.
- Do not freeze.
- Protect from light.

## CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding this document please contact: [Transfusion.SafetyTeam@aplabs.ca](mailto:Transfusion.SafetyTeam@aplabs.ca)

## REFERENCES:

1. Coagadex® Product Monograph. March 2023. [Accessed 25May2024]. [Package Insert - COAGADEX \(fda.gov\)](#)
2. Coagadex® Product Package Insert FXUK4. August 2020.