ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Berinert®
C1 Esterase Inhibitor (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:*** *C1 Esterase Inhibitor* ***Company:*** *CSL Behring* ***Class:*** *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.

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

***Subcutaneous administration is currently considered off-label use and may only occur at the direction of the Rare Blood Disorders / Angioedema Clinic Physician

DESCRIPTION:

- Berinert® C1 Esterase Inhibitor (C1-INH) is a purified, lyophilized concentrate of C1 esterase inhibitor derived from large pools of human plasma.
- Viral inactivation steps include pasteurization, nanofiltration and chromatography.
- Supplied in 500IU and 1500IU dose sizes
  - Berinert® 500 contains 500 IU C1-INH with 10 mL diluent (sterile water for injection)
  - Berinert® 1500 (volume reduced) contains 1500 IU C1-INH (volume reduced) with 3 mL sterile water for injection.
- Also contains glycine, sodium chloride and sodium citrate.
- Latex-free

AVAILABILITY

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

INDICATIONS FOR USE:

- Treatment of acute abdominal, laryngeal or facial attacks of hereditary angioedema (HAE) of moderate to severe intensity in adult and pediatric patients.

CONTRAINDICATIONS:

- Patients who are hypersensitive (allergic) to this blood product or any ingredient in its formulation.

WARNINGS:

- Hypersensitivity reactions may occur.
- The development of thrombosis has been reported when used off-label and at a higher than labeled doses in newborns and young children with congenital heart anomalies during or after cardia surgery under extracorporeal circulation.
- Thrombotic events have occurred in patients at or higher than the recommended dose following treatment of HAE attacks. Patients with known risk factors for thrombotic events should be monitored closely.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MHRP).
- Consult with Hematologist or bleeding disorders clinic
- Treatment for moderate to severe abdominal, facial, and laryngeal HAE attacks:
  - 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
  - Manufacturer recommended dose: 20 units/kg body weight.

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 available. Perform the appropriate pre-transfusion checks per nursing protocol.

Access: Product can be given via peripheral or central venous access site. Subcutaneous administration may be performed at the direction of a hematologist or the bleeding disorders clinic physician.

Reconstitution Supplies:

- Berinert® RT® Product (lyophilized powder)
- Diluent Vial of sterile water for injection (included with product)
- Mix2Vial™ Transfer Device (included with product)
- Alcohol swabs (not included with product)

Administration Supplies:

- Alcohol swabs
- Syringe and Infusion set (included with product)

Reconstitution:

- Ensure the diluent and Berinert® vials are at room temperature
- See *Mix2Vial® Reconstitution Instructions*.

Administration:

- Administer immediately after reconstitution. Do not refrigerate after reconstitution. Discard any unused portions within 4 hours
- Do not mix with any other medications or solutions. Separate infusion line is recommended.
- Do not use solutions that are cloudy, have deposits, or are not colourless
- Administration rate:
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended slow direct IV administration. Suggested rate for Berinert® 500IU is 4mL/min.
  - Consult with hematologist or bleeding disorders clinic for subcutaneous infusion rates.

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.

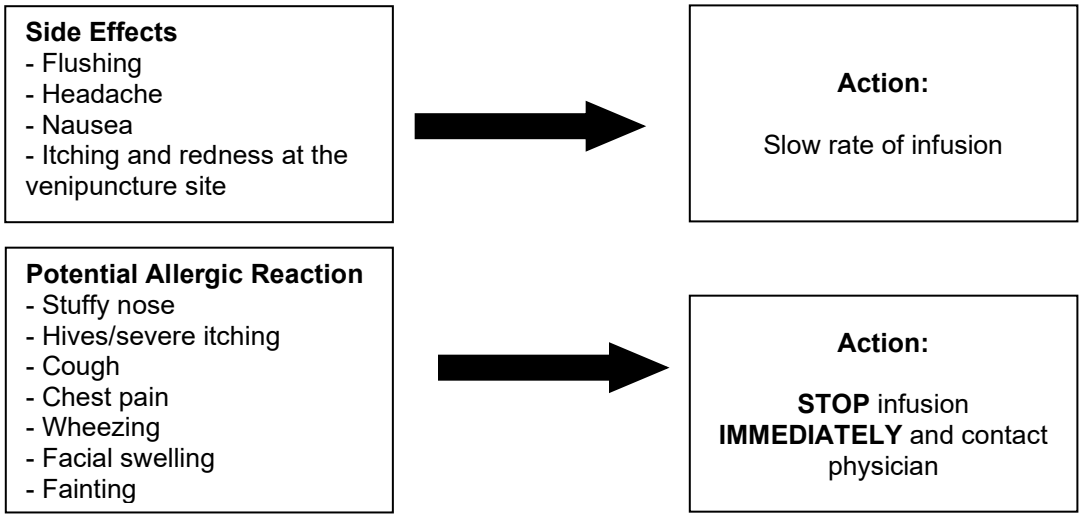
Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up to a transfusion reaction see Transfusion Reactions | Alberta Health Services. Notify 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.

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 serious adverse reaction reported is an allergic-anaphylactic reaction.
- The most commonly reported adverse reaction in patient receiving Berinert® are subsequent HAE attacks, headache, abdominal pain, dysgeusia, nausea, muscle spasm, pain, diarrhea and vomiting.



STORAGE & STABILITY OF PRODUCT:

- Store at 2-30°C until expiry date as indicated on package (36 months from date of manufacture).
- Do not freeze.
- Keep in original carton until ready to use to protect from light.
- Do not use expired product.

CONTACT INFORMATION:

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

REFERENCES:

Berinert® Product Monograph. Available from www.cslbehring.ca