

## Section S: Blood Product Overview – BERINERT®: C1 Esterase Inhibitor CSL Behring

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### DESCRIPTION of PRODUCT

- Lyophilized powder containing approximately 500 U C1 Esterase Inhibitor per vial
- C1 Esterase Inhibitor is prepared from human plasma. Donors have been screened and tested negative for Hepatitis A, B and C, HIV-1/2, and Human Parvovirus B19. Additional virus inactivation steps in the manufacturing include pasteurization, ion exchange chromatography and ammonium sulphate precipitation
- One standard unit of C1 esterase inhibitor concentrate is equal to the amount of C1 esterase inhibitor in 1 mL fresh citrated human plasma, which is equivalent to 270 mg/L or 2.5 micro M/L
- Each vial of Berinert contains 500 units C1 esterase inhibitor, 50 to 80mg total protein, 85 – 115 mg glycine, 70 – 100 mg sodium chloride and 25 – 35 mg sodium citrate
- Each package includes: lyophilized C1 Esterase Inhibitor concentrate, 10 mL diluent (sterile water), one Mix2Vial transfer set, one alcohol swab and package insert.
- Components used in the packaging are latex-free

### AVAILABILITY of PRODUCT

- 4 vials (2000 U) are stocked in the Blood Transfusion Laboratory (BTL) at both University and Victoria Hospitals, LHSC
- Not stocked in the BTL at SJHC
- Additional product can be obtained through the BTL from the Canadian Blood Services (CBS)

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### STORAGE of PRODUCT

- Stored at 2 - 25°C. Do NOT freeze. Protect from light.
- Expiration date is indicated on bottle.
- After reconstitution, C1 Esterase Inhibitor must be administered immediately. Reconstituted product does not contain any preservatives, so must be discarded within 8 hours if unused.

### CLINICAL INDICATIONS (see package insert for contraindications)

- Hereditary angio-edema (HAE) (Previously known as angioneurotic edema)
- Berinert is indicated for the treatment of acute abdominal or facial attacks of Hereditary Angioedema (HAE) in adult and adolescent patients
- May also be required prophylactically before surgery or procedure

### REQUESTS for C1 Esterase

- Hematologist approval not required for confirmed Hereditary Angioedema patients.
- All other requests must be approved by a Hematologist.

### ADMINISTRATION of PRODUCT

- Administer Berinert at a dose of 20 units per kg body weight rounded up or down to the nearest number of vials (each vial = 500 units)
- Berinert is reconstituted and pre-filtered in the BTL and issued in a syringe.
- Should be given by slow intravenous injection at a rate of approximately 4mL per minute
- The following article refers to the administration of C1 Esterase Inhibitor by diluting the reconstituted product in 50 mL saline-D5/W and infusing over a period of 15 – 30 minutes:  
Visentin DE, Yang WH, Karsh J. C1-esterase inhibitor transfusions in patients with hereditary angioedema. Ann Allergy Asthma Immunol 1998;80:457-61.

### ADDITIONAL COMMENTS

- Website on Hereditary Angioedema (HAE) for HealthCare Professionals and patients:  
<http://www.allabouthae.com/>.

### LINK to WEBSITE for PRESCRIBING INFORMATION

Product monograph available at:  
[http://www.berinert.com/docs/berinert\\_pi.pdf](http://www.berinert.com/docs/berinert_pi.pdf)

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