

TRANSFUSION MEDICINE SERVICES

<b>OTHER NAMES</b> C1-INH	<b>CLASSIFICATION</b> C1 Esterase Inhibitor	<b>ALERTS</b> Contains human plasma
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**PREPARATION and ADMINISTRATION**

**Reconstitution**

Diluent: sterile water for injection in 3 mL (1500 units/vial) and 10 mL (500units/vial) volumes

See page 3–5 for reconstitution steps

The reconstituted solution for Berinert 500 should be colorless and clear. The reconstituted solution for Berinert 1500 should be colorless, clear to slightly opalescent. Do not use if the solution is cloudy or contains particulates.

Reconstituted solution may be administered IV Direct (professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently).

Otherwise administer with a syringe pump (less than 60 mL) or inject solution into an emptied IV bag and infuse via volume pump.

IV Direct	Intermittent Infusion	Continuous Infusion
As per employment authorization and skillset	<b>IV Bag (large volume pump)</b>	<b>IV Bag (large volume pump)</b>
<b>RECOMMENDED ROUTE</b>  Administer IV Direct at 2 mL/min, increasing to <b>4 ml per minute (max)</b> , as tolerated.	Not Recommended	Not applicable
	<b>Syringe (syringe pump)</b>	<b>Syringe (syringe pump)</b>
	Not Recommended	Not applicable

**Requirements and Monitoring**

Thrombotic events have been reported at the recommended dose of C1 Esterase Inhibitor (Human) products, including Berinert, following treatment of HAE attacks.

If transfusion is less than 15 minutes: check vital signs before initiation (baseline), on completion, and with any development of signs/symptoms of an adverse event. **Document all vitals taken.**

Blood pressure via cuff or arterial line

Temperature

Heart Rate

Respirations

Lung sounds in non-verbal, non-oriented or pediatric patients and patients with CHF or pulmonary dysfunction

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

**INDICATIONS**

Berinert is indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) of moderate to severe intensity in pediatric and adult patients.

The safety and efficacy of Berinert for prophylactic therapy has not been established.

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### ADVERSE EFFECTS

**Adverse reactions may include:** Allergic-type hypersensitivity reactions including anaphylaxis have been reported and have manifested as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.

If an AE is suspected: stop the transfusion, disconnect and cap the blood tubing, initiate the backup line of NS and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume transfusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once transfusion is discontinued or completed.

### DOSAGE

The recommended dose of Berinert® in the treatment of abdominal, facial and laryngeal HAE attacks of moderate to severe intensity is 20 units per kg body weight.

### COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expire date
- Do not dilute in any IV solutions
- Protect vials from light
- Do not store unused vials in refrigerator. Administer at room temperature

### DOSAGE FORMS

- Supplied by Transfusion Medicine

### MISCELLANEOUS





- None

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**RECONSTITUTION**

Use the Mix2Vial® filter transfer set provided with Berinert® (see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section) or any double-ended needle and vented filter spike if Mix2Vial® is not used. Use the syringe provided with the product.

Follow the steps below and use aseptic technique to administer Berinert®.		
<b>A</b>	<b>PREPARATION:</b> Prepare the vials/Mix2Vial® and infusion supplies: <b>Ensure that the diluent and Berinert® vials are at room temperature.</b> Prepare syringes, infusion sets and other supplies for the infusion.	
<b>B</b>	<b>RECONSTITUTION:</b> Don clean gloves and follow these steps to reconstitute Berinert®:	
1	<b>Clean Stoppers</b> Remove the flip caps from both vials (Berinert® and diluent). Wipe rubber stoppers with an antiseptic and allow the rubber stopper to dry.	Diluent Vial Berinert® Vial 
2	<b>Open the Mix2Vial® package</b> by peeling away the lid. To maintain sterility, leave the Mix2Vial® set in its clear outer package.	
3	<b>Prepare Diluent Vial:</b> Place the diluent vial on an even flat surface and hold the vial tightly. Grip the Mix2Vial® keeping it in the package. Push the plastic spike of the blue end of the Mix2Vial® set firmly through the center of the diluent vial stopper.	
4	<b>Remove the Mix2Vial® packaging:</b> While holding the diluent vial, carefully remove the outer package from the Mix2Vial® set. Make sure to pull off only the package, not the Mix2Vial® set.	

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5	<p><b>Transfer Diluent into Beriner<sup>®</sup>t Vial:</b> Place the product vial on an even flat surface and hold the vial tight. Invert the diluent vial with the Mix2Vial<sup>®</sup> set attached to it and push the plastic spike of the clear end of the Mix2Vial<sup>®</sup> end firmly through the stopper of the Beriner<sup>®</sup>t vial. The diluent will transfer into the Beriner<sup>®</sup>t vial automatically.</p>	
6	<p><b>Dissolve Beriner<sup>®</sup>:</b> With the diluent and Beriner<sup>®</sup> vial still attached to the Mix2Vial<sup>®</sup> set, gently swirl the Beriner<sup>®</sup> vial to ensure the product is fully dissolved (note: Beriner<sup>®</sup> 1500 may take longer than Beriner<sup>®</sup> 500 to dissolve). Do not shake the vial.</p>	
7	<p><b>Unscrew empty diluent (Blue) vial:</b> With one hand, grip the clear end of the Mix2Vial<sup>®</sup> set and with the other hand grip the blue end of the Mix2Vial<sup>®</sup> set and unscrew the set into 2 pieces.</p>	
8	<p><b>Load the syringe:</b> Draw air into an empty, sterile syringe. Use the syringe provided with the product. With the Beriner<sup>®</sup> vial upright, screw the syringe to the Mix2Vial<sup>®</sup> set. Inject air into the product vial (Fig. A). While keeping the syringe plunger pressed, invert the Beriner<sup>®</sup> vial and draw the solution into the syringe by pulling the plunger back slowly. (Fig. B).</p>	<p>Fig. A      Fig. B</p> 
9	<p><b>Prepare administration set equipped with microbore tubing:</b> Once the solution has been transferred into the syringe, firmly grip the barrel of the syringe (keeping the plunger facing down) and unscrew the syringe from the Mix2Vial<sup>®</sup> set. Attach the syringe to an infusion set or another suitable administration set.</p>	

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<b>C</b>	<p><b>Administer Berinert® using aseptic technique:</b></p> <ul style="list-style-type: none"> <li>• Thoroughly wash and dry hands.</li> <li>• Locate vein.</li> <li>• Clean the injection site(s) using an antiseptic skin preparation. Allow each site to dry before proceeding.</li> <li>• Insert the needle into the vein.</li> <li>• Check for proper placement of the needle.</li> <li>• Inject Berinert® 500 into the vein using a slow intravenous injection (4mL/minute). Inject Berinert® 1500 into the vein using a slow intravenous injection.</li> </ul>
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## REFERENCES

- [CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure](#)
- Berinert product monograph. Found at <https://www.cslbehring.ca/products/product-list>