

**Training Guide  
for Berinert®  
(C1 esterase inhibitor, Human)  
Self-Administration**



# Introduction

The Berinert home-based IV (intravenous) self-administration program is intended to train patients in self-infusion techniques.

The program is intended to help you to self-administer IV doses of C1-esterase inhibitor (Berinert) according to the instructions provided by your doctor.

This training course and the materials associated with this course are to be provided by a trained healthcare professional.

## The CSL Behring Patient Portal

Visit [patients.cslobehring.ca](https://patients.cslobehring.ca) to access tools and resources to support you at every step along your **Berinert treatment journey**. *You will need to enter the 8-digit DIN located on your Berinert package to enter the site.*



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# My Healthcare Team

Contact	Name	Contact Number
Clinic Nurse		
Doctor		
Emergency Department		
Blood Bank		
Other Relevant Contacts		

## Getting Your Berinert

Berinert is a plasma-derived C1-esterase inhibitor which is typically distributed by a blood bank.

Instructions may differ at each centre as to where and how to pick up your Berinert supply. Please follow the instructions outlined by your healthcare professional to obtain your Berinert supply.

# Training Requirements

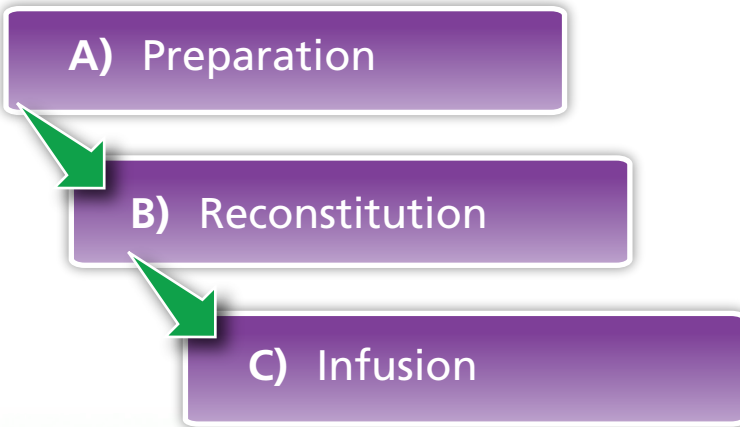
Certain training requirements should be met before attempting self-administration of Berinert at home. The following are some of the requirements:

- Attend training session(s) given by a healthcare professional.
- Master the following techniques:
  - Clean/aseptic technique.
  - Proper handling and storage.
  - Prepare Berinert.
  - Independent insertion of IV butterfly needle.
  - Infuse Berinert.
  - Proper waste disposal.
  - Recording infusion.

# The ABCs of Berinert SELF-ADMINISTRATION

Your prescribing physician will discuss with you when to infuse your C1-Inhibitor concentrate and the appropriate dose to use.

This Step-By-Step Guide will teach you the proper techniques for self-administering Berinert:





# A. PREPARATION

## 1. Assemble Supplies

- ✓ Berinert + Diluent (Sterile Water for Injection) Vials.  
*Ensure that the diluent and Berinert vials are at room temperature.*
- ✓ Mix2Vial®.
- ✓ Disposable syringe(s).  
Use syringe that was provided with the product.
- ✓ Butterfly infusion set(s).
- ✓ Tourniquet.
- ✓ Disinfection swabs, such as alcohol swabs.
- ✓ Sterile gauze pads.
- ✓ Surgical/paper tape (if required).
- ✓ A1 bandage (if required).
- ✓ Sharps/Biohazard container.





# Berinert 500 Package

## Product Pack

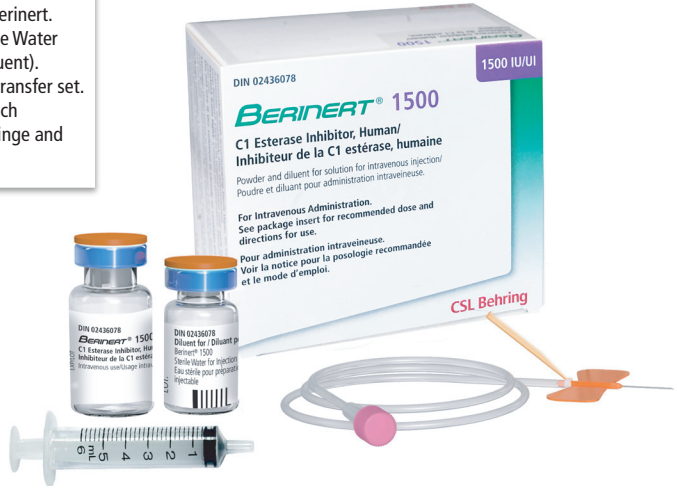
- 500 IU vial of Berinert.
- 10 ml vial of Sterile Water for Injection (Diluent).
- Mix2Vial® filter transfer set.
- Inner Carton which contains: one syringe and one infusion set.



# Berinerter 1500 Package

## Product Pack

- 1500 IU vial of Berinert.
- 3 ml vial of Sterile Water for Injection (Diluent).
- Mix2Vial® filter transfer set.
- Inner Carton which contains: one syringe and one infusion set.



# A. PREPARATION

## 2. Prepare Supplies

- Ensure that the diluent and Berinert vials are at room temperature.
- Prepare syringes (use the syringe provided with the product), infusion sets and other supplies for the infusion.

## 3. Clean Hands

- Thoroughly wash and dry your hands (Figure 1).



# B. RECONSTITUTION

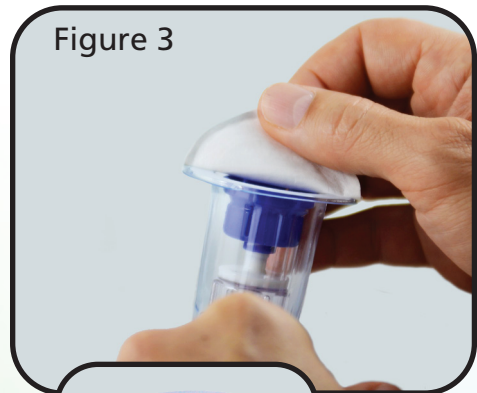
## 1. Clean Stoppers

- Inspect each product vial.
- Check expiration date.
- Ensure the caps are secure.
- Remove the flip caps from both vials (Berinert and diluent).
- Wipe rubber stoppers with an antiseptic and allow the rubber stopper to dry (Figure 2).



## 2. Open the Mix2Vial® Package

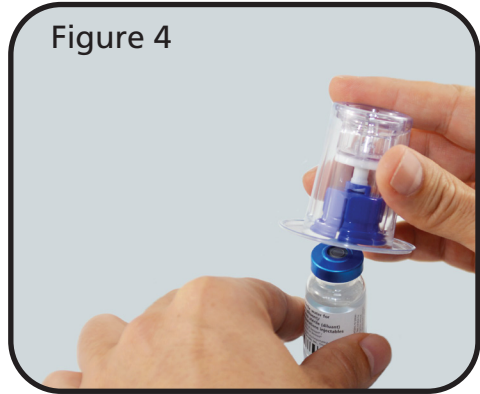
- Peel away the lid (Figure 3).
- To maintain sterility, leave the Mix2Vial® set in its clear outer package.



# B. RECONSTITUTION

## 3. Prepare Diluent/Sterile Water Vial

- 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 centre of the diluent vial stopper (Figure 4).
- The blue end locks onto the diluent vial with a “click”.



## 4. Remove the Mix2Vial® Packaging

- While holding the diluent vial, carefully remove the outer packaging from the Mix2Vial® set.
- Make sure to pull off only the package, not the Mix2Vial® set (Figure 5).



# B. RECONSTITUTION

## 5. Transfer Diluent/Sterile Water into Berinert Vial

- Place the product vial on an even flat surface and hold the vial tight.
- Invert the diluent vial with the Mix2Vial® set attached to it and push the plastic spike of the clear end of the Mix2Vial® end firmly through the stopper of the Berinert vial (Figure 6).
- The transparent end locks onto the product vial with a “click”.
- The diluent will transfer into the Berinert vial automatically.

Figure 6



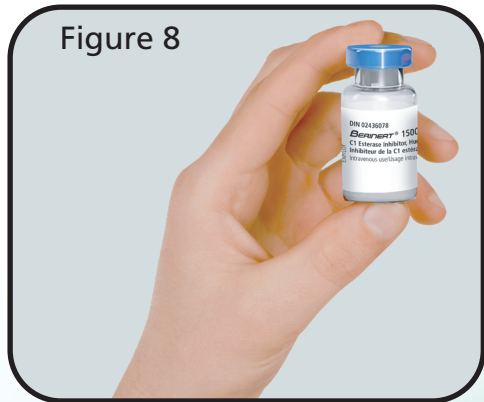
# B. RECONSTITUTION

## 6. Dissolve Berinert

- With the diluent and Berinert vial still attached to the Mix2Vial® set, gently swirl the Berinert vial to ensure the product is fully dissolved (note: Berinert 1500 may take longer than Berinert 500 to dissolve) (Figure 7).



- Do not shake the vial.
- The reconstituted solution for **Berinert 500** should be colourless and clear. The reconstituted solution for **Berinert 1500** should be colourless, clear to slightly opalescent.
- Inspect Berinert visually for particulate matter and discolouration prior to administration (Figure 8).
- Do not use if the solution is cloudy or contains particulates.



# B. RECONSTITUTION

## 7. Unscrew Empty Diluent (Blue) Vial

- With one hand, grip the clear end of the Mix2Vial® set and with the other hand grip the blue end of the Mix2Vial® set (Figure 9).
- Unscrew the set into two pieces.

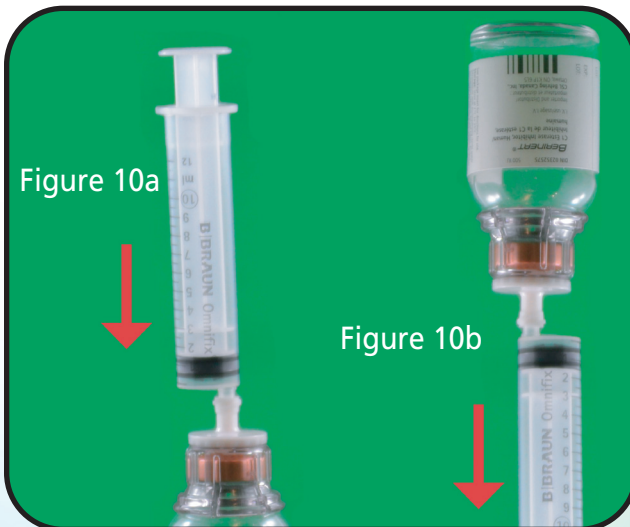




# B. RECONSTITUTION

## 8. Load the Syringe

- Draw air into an empty, sterile syringe. Use the syringe provided with the product.
- With the Berinert vial upright, screw the syringe to the Mix2Vial® set.
- Inject air into the product vial (Figure 10a).
- Keeping the syringe plunger pressed, invert the Berinert vial and draw the solution into the syringe by pulling the plunger back slowly (Figure 10b).

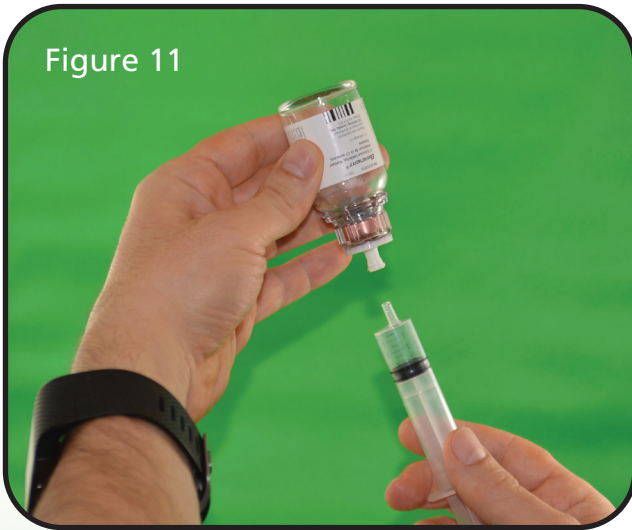


## B. RECONSTITUTION

### 9. Prepare Administration Set Equipped With Microbore Tubing

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® set (Figure 11). Attach the syringe to an infusion set or another suitable administration set.

Figure 11



## B. RECONSTITUTION – Troubleshooting

If you lose the vacuum within the sterile environment or if the Mix2Vial® is not available; please use a another vial to ensure a full dose and contact your training nurse educator.

# C. SELF-ADMINISTRATION

Your healthcare professional will teach you how to safely infuse Berinert. It is important that Berinert is injected directly into a visible vein. Do not inject into surrounding tissues or into an artery. Once you learn how to self-infuse, follow the instructions provided.

## Assemble Supplies

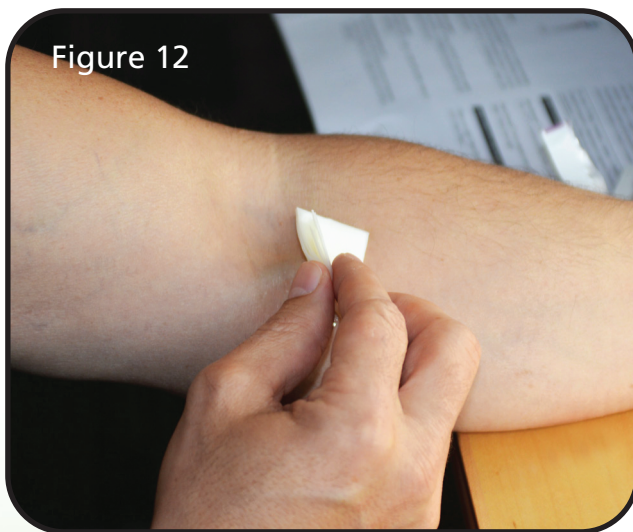
- Syringes filled with Berinert.
- Butterfly needle infusion set.
- Tourniquet.
- Alcohol swab.
- Sharps/biohazardous container.
- Other supplies as recommended by your healthcare professional.



# C. SELF-ADMINISTRATION

## Prepare the Infusion Site:

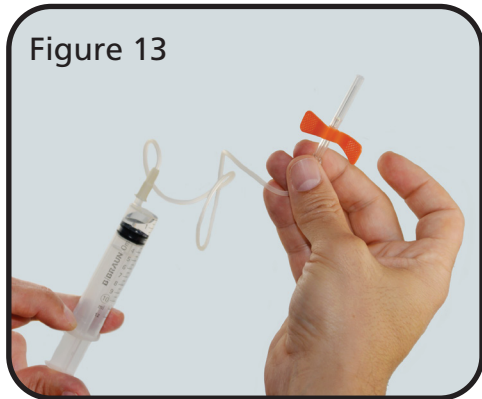
- Apply a tourniquet on the arm above the site of the injection.
- Prepare the injection site by wiping the skin well with an alcohol swab (Figure 12).



# C. SELF-ADMINISTRATION

## Infuse Product As Instructed by Your Healthcare Professional:

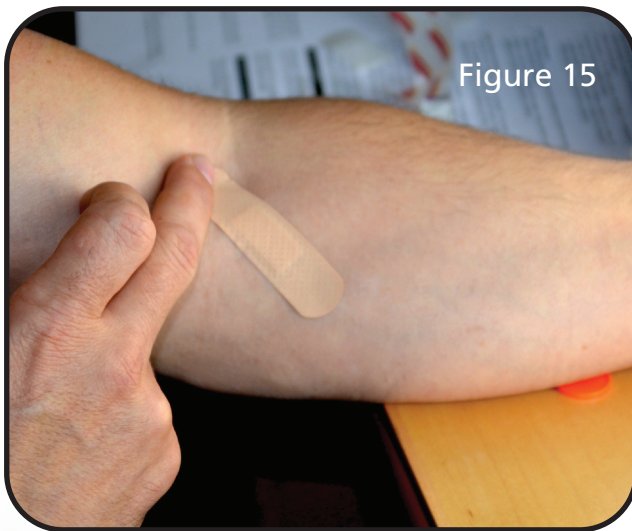
- Remove the air from the tubing (Figure 13).
- Insert the butterfly needle of the infusion set into your vein (Figure 14).
- Remove the tourniquet.
- If necessary, use tape or transparent dressing to hold the needle in place.
- Inject the **Berinert 500** solution slowly at a rate of approximately 4 mL per minute or inject the **Berinert 1500** solution as a slow intravenous injection.



# C. SELF-ADMINISTRATION

## Complete Infusion

- After infusing Berinert, remove the infusion set.
- Cover the infusion site with a bandage (Figure 15).



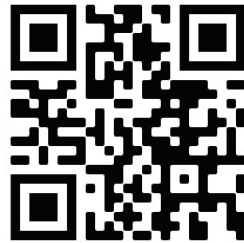
## Clean-Up

- Dispose of all unused solution, the empty vials and the used needles and syringe into an appropriate container.

# C. SELF-ADMINISTRATION

## Record Treatment

- You may use the HAERO app to track and record your treatments.
- Download the HAERO app from the App store or Google play to track your attacks and treatment.



# SAFETY FIRST

The following section describes the potential side effects associated with Berinert and what to do in case of an emergency.

Remember, you are not alone. If at any point you do not feel you can infuse your product, go to your hospital for assistance.

## CLINICAL USE

### **Berinert (C1 Esterase Inhibitor, Human) Is Used:**

For the treatment of acute facial, abdominal and laryngeal hereditary angioedema (HAE) attacks of moderate and severe intensity in pediatric and adult patients.

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

### **When It Should Not Be Used:**

Berinert should not be used if you had previous severe allergic or body reactions to C1-INH products used to treat HAE or any components of Berinert.



# WARNINGS AND PRECAUTIONS

## Serious Warnings and Precautions

Products made from human plasma may contain infectious agents such as viruses and the agent responsible for the variant Creutzfeldt-Jakob disease (CJD).

- Thrombotic events have been reported with the use of Berinert at the recommended dose following treatment of HAE attacks.
- The development of thrombosis has been reported in association with Berinert when used (off-label) and at higher than labeled doses (greater than 90 IU/kg body weight) in newborns and young children with congenital heart anomalies during or after cardiac surgery under extracorporeal circulation.

### BEFORE You Use Berinert Talk to Your Doctor or Pharmacist If:

- You have any special heart conditions.
- You have experienced severe allergic reactions or other reactions with products used to treat your HAE condition or if you have experienced allergic reactions to this drug or its ingredients or components of the container.
- You are pregnant or if you are breastfeeding.

# Very Common and Common Side Effects

SIDE EFFECTS*, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom/effect	Talk with your doctor or pharmacist		
	Only if severe	In all cases	
Headache	√		
Abdominal pain <sup>†</sup>	√		
Nausea <sup>†</sup>	√		
Muscle spasms	√		
Pain			
Diarrhea <sup>†</sup>	√		
Vomiting <sup>†</sup>	√		
Back pain	√		
HAE		√	
Peripheral edema		√	
Abdominal distention		√	
Upper respiratory tract infection		√	
Dysgeusia		√	

*NOTE: This is not a complete list of side effects. For a complete list, please refer to your medication leaflet.*

*\* Reported in a key clinical study, related or not related to Berinert.*

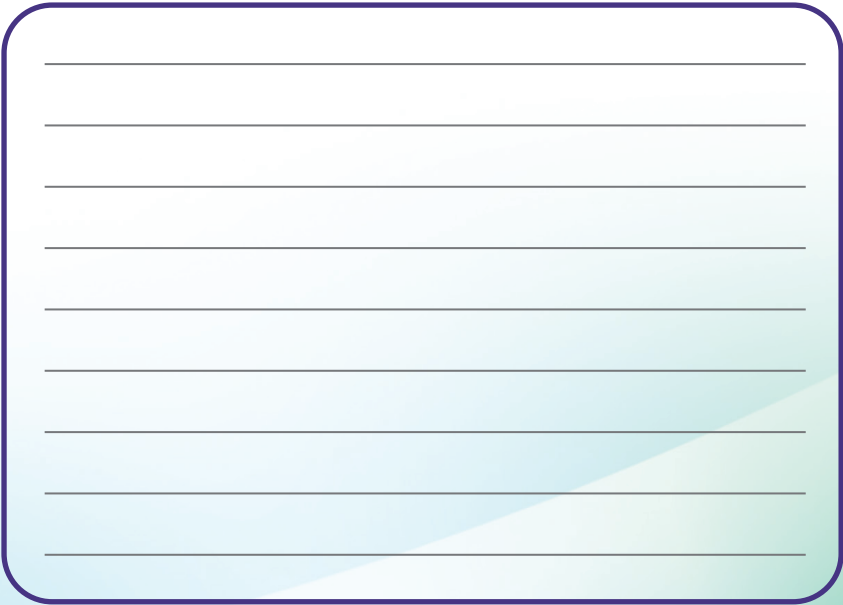
*<sup>†</sup> Symptoms were considered to be related to the underlying disease. Any increase in intensity or new occurrence of these symptoms after study medication administration was considered to be an adverse event.*

# EMERGENCY PROCEDURES

## In Case You Can't Self-Infuse Berinert

- If you are unable to start your self-infusion of Berinert please proceed to the Emergency Department or other designated place provided by your healthcare professional in order to get assistance with the infusion of your product.
- Your healthcare professional may recommend taking the vials of Berinert with you to the Emergency Department.
- Your healthcare professional may also recommend taking your wallet card.

## Additional Emergency Procedures:



A large rounded rectangular box with a dark blue border, containing ten horizontal lines for writing.

# EMERGENCY PROCEDURES

## Continued

In case of drug overdose, contact a healthcare professional, hospital Emergency Department or regional Poison Control Centre immediately, even if there are no symptoms.

### Additional Emergency Procedures:

A large rounded rectangular box with a purple border, containing ten horizontal lines for writing.

# EMERGENCY PROCEDURES

## Continued

### Emergency Wallet Cards

<https://haecanada.org/wp-content/uploads/sites/64/2022/01/2022-CHAEN-ID-card.pdf>

## Emergency Management of Hereditary Angioedema (HAE)

Developed by the Canadian Hereditary Angioedema Network (CHAEN) representing HAE physicians | [chaen-rcah.ca](http://chaen-rcah.ca)

**PATIENT IDENTIFICATION**

Name \_\_\_\_\_

Date of Birth \_\_\_\_\_

Health System # \_\_\_\_\_

**DIAGNOSIS**

HAE is a rare potentially life-threatening disease usually caused by C1 inhibitor (C1-INH) deficiency associated with tissue swelling (see description below).

**PROMPT TREATMENT**

**PROMPT TRIAGE & ASSESSMENT**

To determine the severity of the swelling.

**PROMPT TREATMENT**

Will rapidly initiate onset of relief of the angioedema in this patient and decrease morbidity and mortality.

**AIRWAY OBSTRUCTION**

The risk of dying from airway obstruction if left untreated is significant. Consider **early intubation** in progressive laryngeal edema.

**Clinical Characteristics of HAE**

Recurrent non-pruritic edema of skin and submucosal tissue associated with pain, nausea/vomiting, diarrhea and airway swelling which can be life threatening.

- Laryngeal/airway swelling
- Facial/neck swelling
- Abdominal attacks (abdominal pain, cramping, diarrhea, nausea/vomiting)
- Peripheral edema (other regions)

**PROMPT TREATMENT REQUIRED to PREVENT RAPID DETERIORATION**

**RECOMMENDED TREATMENT**

C1 inhibitor (IV): 20 units/kg  
Dose for this patient is \_\_\_\_\_ units IV by slow push (available at Blood Bank or patient will carry).

Icatibant: 30mg in 3cc subcutaneous injection over 30 seconds from a prefilled syringe.

Only if above not available, consider: solvent detergent treated plasma (SDP) or less safe frozen plasma (2 Units).

HAE attacks usually do not respond to treatment with glucocorticoids, antihistamines or epinephrine. This patient may require prophylaxis before surgery or dental procedures in order to prevent an angioedema attack.

**HEALTHCARE TEAM**

In case of Emergency Contact my Physician:

MD/specialty \_\_\_\_\_

Hospital \_\_\_\_\_

📞 \_\_\_\_\_

Other Clinic / Physician:

MD/specialty \_\_\_\_\_

Hospital \_\_\_\_\_

📞 \_\_\_\_\_

Physician signature \_\_\_\_\_

Date of recommendation: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Day / Month / Year

**EMERGENCY CONTACTS**

Please Contact:

Name \_\_\_\_\_

Relationship \_\_\_\_\_

📞 \_\_\_\_\_

Other Recommendations / Comments:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

References:  
CHAEN/RCAH WEBSITE FOR EMERGENCY TREATMENT  
[chaen-rcah.ca/guidelines](http://chaen-rcah.ca/guidelines)

 Canadian HAE Patient Organization | [haecanada.org](http://haecanada.org)

# How to Store Berinert

Store Berinert in the refrigerator or at room temperature (at +2°C to +30°C). Do not use the product after the expiration date.

Keep Berinert in its original carton until ready to use. Do not freeze. Protect from light.

Avoid extreme temperatures (outside the range indicated above). See some examples of extreme temperatures:



# Traveling With Berinert

## Tips

- Take an adequate quantity of Berinert product and supplies (for example: Syringes, Mix2Vial®, etc.) to cover treatment during your traveling period. Discuss with your healthcare professional how many doses you should always keep with you.
- The product must be kept at +2°C to +30°C:
  - It must be protected from temperature extremes.
- Take a copy of your prescription for Berinert with you (if required).
- Also take any other documentation you may need such as:
  - Wallet Card. *See page 29.*
  - Infusion diary/log sheets.
- Ask your healthcare professional for a travel letter.
- Always keep your Berinert in your carry-on bag, not in your checked luggage.

CSL Behring

**PLUS**<sup>™</sup>  
PATIENT SUPPORT PROGRAM



## A Program Designed To Facilitate Your Treatment Journey With Berinert

### STEP 1 Enrolment

After you have been prescribed Berinert and you have been enrolled into the CSL Behring PLUS+ program by your healthcare professional, a Nurse Case Manager will call you to:

- Explain the program.
- Describe the services.
- Ask you questions about your medical history.
- Provide information about your treatment.

### STEP 2 Ancillaries

As part of its enhanced program services, CSL Behring PLUS+ is providing ancillary supplies to all patients registered with the program at no cost.





## STEP 3 Obtaining Berinert

Once you are ready to begin your training:

- Your Nurse Case Manager will coordinate your Berinert pickup with the blood bank. A blood bank is a department within the hospital that stores and distributes Berinert.

## STEP 4 Training and Ongoing Nurse Support

Our program team will provide you with:



- Information on Berinert.
- Unlimited one-on-one training to help you learn to administer Berinert at the clinic or in the comfort of your home.
- Ongoing support, education and training throughout the course of your therapy.

## STEP 5 Reports to Physician

Our program team will send:

- Reports to the blood bank when you are trained.
- Summary notes for your physician at every touchpoint.

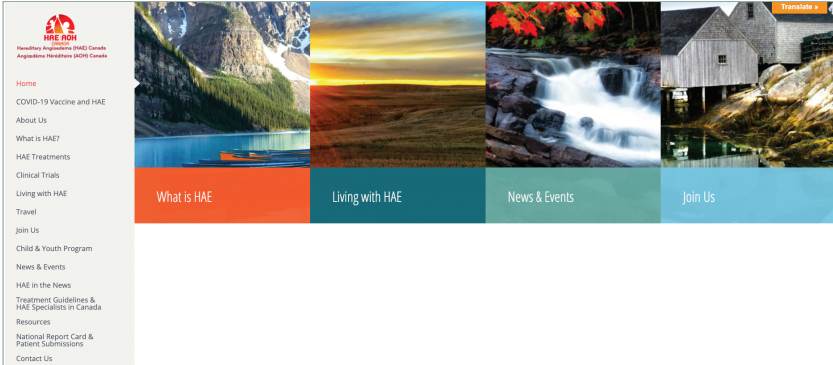


If you have any questions about Berinert or the CSL Behring PLUS+ Program, please email [cslbehringplus@bayshore.ca](mailto:cslbehringplus@bayshore.ca) or call 1-888-490-4105, Monday to Friday from 8 AM-8 PM EST. Alternatively, you can contact your healthcare professional.

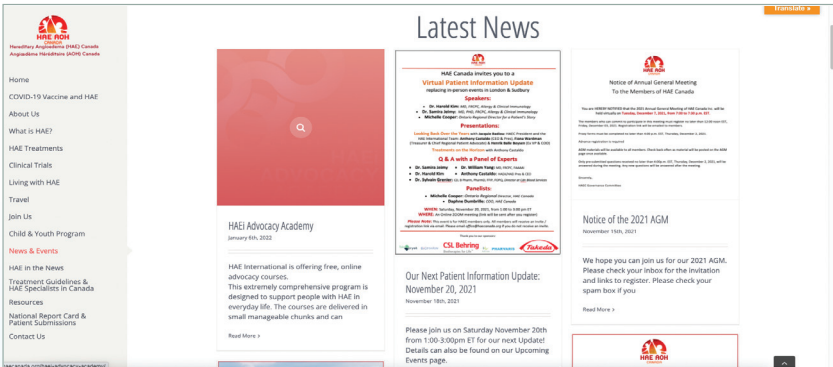


# RESOURCES

Website: [haecanada.org](http://haecanada.org)



## Latest News and Events\*



*\*CSL Behring Canada is not responsible for the information content/ recommendations of these resources, which are provided for supplementary information only.*









Beriner<sup>®</sup> is a registered trademark of  
CSL Behring GmbH.

Beriner<sup>®</sup> is manufactured by CSL Behring GmbH  
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Biotherapies for Life<sup>®</sup> is a registered trademark of  
CSL Behring LLC.

Mix2Vial<sup>®</sup> is a registered trademark of West Pharma.  
Services IL, Ltd., a subsidiary of West Pharmaceutical  
Services Inc.

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