

Overview of Nurse Responsibility in Patient Training



Introduction

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

The program enables 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.

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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 the Blood Bank.

Instructions may differ at each center 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.

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By providing the appropriate training and support, the nurse can be key in helping the patient to take ownership of their Berinert® treatment. Ensuring the healthcare team contact information is available to the patient provides added resources while the patient is transitioning to home administration.

Discuss who to call for questions.

- Clear and written patient discharge instructions
- Contact numbers
- See Consumer Information provided with the Berinert® package, or Part III of the Product Monograph

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.
 - Insertion of an intravenous (IV) butterfly needle.
 - ability to independently insert IV butterfly into a vein on each arm.
 - Prepare and infuse Berinert®.
 - Proper waste disposal.
 - Recording infusion.

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Training Requirements

- It is important to help manage patient expectations on Berinert® therapy so that they are better prepared when variabilities arise, and less likely to be non-adherent to therapy
- Explain benefits and risks of Berinert® therapy/reasons for choice
- Set expectations:
 - How long an infusion takes
 - Necessary equipment
 - Transition/adjustment period to home infusion therapy

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. https://www.allabouthae.ca/docs/HAE_WalletCard.pdf
 - 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.

The ABC's 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

B) Reconstitution

C) Infusion

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A. PREPARATION

- Prepare a clean, even, flat surface, such as an infusion mat.
- Clean surface with antiseptic wipe.
- Ensure that the diluent and product vials are at room temperature.
- Prepare syringes (use the syringe provided with the product), infusion sets and other supplies for the infusion.



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Preparation

Clean Surface

Instruct the patient to locate a flat, non-porous surface/ infusion mat and clean the area with an alcohol wipe/ disinfectant wipe in a circular motion, starting in the centre and working outward.³

<https://www.publichealthontario.ca/-/media/documents/bp-environmental-cleaning.pdf>

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).
- ✓ 1 bandage (if required).
- ✓ Sharps/Biohazard container.
- ✓ HAE patient diary/log sheets.



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Preparation

Assemble Supplies

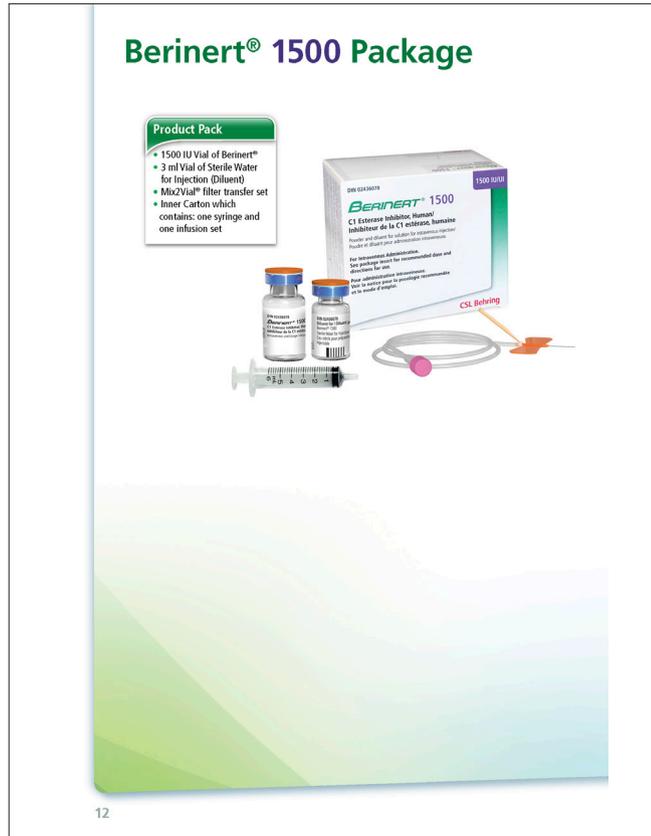
Instruct the patient to assemble all the supplies needed for treatment. The patient should also have extra supplies on hand in case of contamination.

Beriner[®] 500 Package

Product Pack

- 500 IU Vial of Beriner[®]
- 10 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

- Clean your hands by rubbing them with an alcohol-based formulation (hand sanitizer containing 70% alcohol is preferred for routine hand hygiene), if hands are not visibly soiled.
- When hands are visibly dirty, wash your hands with soap and water (Figure 1).



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Preparation

Thoroughly wash and dry your hands.

Instruct the patient to thoroughly wash and dry hands. Check your institution's guidelines to confirm their recommended length of time and method of contamination prevention. Some examples include: aseptic technique, minimum 20 seconds, 2 "Happy Birthdays", or the use of paper towels to turn off taps, etc.

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).



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.

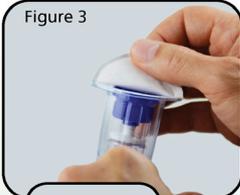


Figure 3

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Inspection of the vial:

- No cracks or damage to the vials
- Protective caps intact
- If the vial or protective cap is damaged, do not use. Return vial to the TMS/Blood Bank.

When cleaning the rubber stoppers, use one antiseptic wipe per vial, ensuring aseptic technique.

Remove the Mix2Vial® Packaging

Ensure the patient does not touch the spike in the blue top.

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 center 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).



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Remove the Mix2Vial® Packaging

When removing the packaging, ensure the patient does not touch the exposed spike in the clear end.

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



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Transfer Diluent/Sterile Water into Berinert® Vial

The Mix2Vial® should be aligned completely vertical before piercing the rubber stopper. The vacuum in the Berinert® vial will allow the diluent to transfer into the Berinert® vial automatically. The vacuum loss may occur if the spike is inserted at an angle.

If the fluid does not transfer automatically, instruct the patient to contact the training nurse for further instructions.

Instruct the patient to use new vials of Berinert® and diluent if the diluent does not transfer into the Berinert® powder.

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.



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Dissolve Berinert®

Allow the concentrate to fully dissolve. Berinert® 1500 IU may take longer to dissolve than the 500 IU.

B. RECONSTITUTION

7. Unscrew Empty Diluent/ Sterile Water 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.

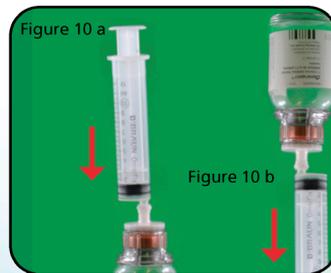


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B. RECONSTITUTION

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 10 a).
- Keeping the syringe plunger pressed, invert the Berinert® vial and draw the solution into the syringe by pulling the plunger back slowly (Figure 10 b).



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Load the Syringe

The syringe provided in the Berinert® packaging is a slip-tip silicone-free syringe.

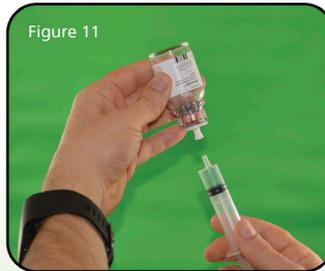
The slip-tip is provided to ease removal of syringe from infusion butterfly if multiple syringes are needed to achieve the required dose.

B. RECONSTITUTION

9. Prepare administration set equipped with microbore tubing (butterfly infusion set)

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 contact your training nurse educator.

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Prepare Administration Set

Ensure patient has the infusion butterfly prepared to attach to the Berinert® filled syringe to avoid contamination of the syringe.

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.
- Treatment diary/log book.
- 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. Use a circular motion starting from the center and working outward. Your healthcare professional may recommend allowing the site to dry completely before proceeding to the next step (Figure 12).

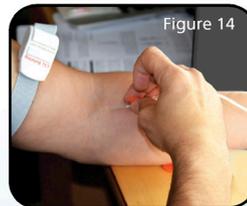


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C. SELF-ADMINISTRATION

Infuse product as instructed by your healthcare professional:

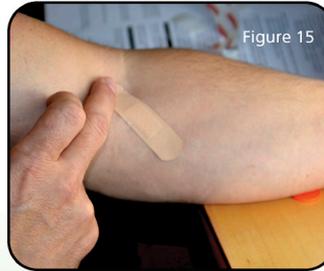
- Remove the air from the tubing (Figure 13).
- Insert the butterfly needle of the infusion set into your vein (Figure 14).
- Remove the tourniquet.
- If necessary, use tape or transparent dressing to hold the needle in place.
- Inject the **Beriner® 500** solution slowly at a rate of approximately 4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



C. SELF-ADMINISTRATION

Complete Infusion

- After infusing Berinert®, remove the infusion set and apply pressure on the site, if recommended by your healthcare professional.
- Cover the infusion site with a bandage.



Clean-up

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

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How to dispose of a full sharps container

Ensure the lid is closed tightly. DO NOT dispose of a sharps container in regular garbage or recycling. The patient should be instructed to check with their municipality to determine their local policy regarding sharps containers.

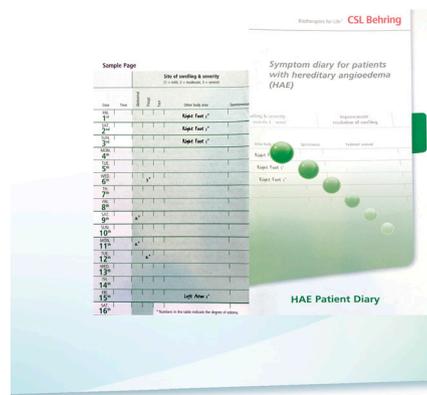
C. SELF-ADMINISTRATION

Record Treatment

Enter each infusion in your Patient Diary/log book.

- Record the lot number from the Berinert® vial label.
- Write down the date and time of your infusion, and any other important details.

Be sure to tell your doctor about any problems you have during your infusions. Your doctor may also ask to see your Patient Diary, so take it with you each time you visit your doctor's office.



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Record the Infusion

Discuss the importance of documentation of all information, including lot numbers. Documentation of attacks helps to ensure best treatment for the patient. It also tracks the product in case of recall.

C. SELF-ADMINISTRATION

Record Treatment

- You may also 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.



The image shows a slide with a white background and a green and blue gradient at the bottom. It features the HAERO logo, which consists of a stylized blue figure inside a circle, with the word "HAERO" in blue capital letters below it. To the right of the logo is a black and white QR code. The slide is numbered "26" in the bottom left corner.

Record Treatment

If Patient interested: Explain that the AOH Haero App can easily and conveniently capture all their HAE health history in one convenient place and all of it on the same platform they use for so many other aspects of their life - their smartphone!

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® is used:

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®

*An HAE attack of moderate intensity is characterized by a degree of discomfort caused by clinical HAE symptoms that results in some interference with daily activities. An HAE attack of severe intensity is characterized by a degree of discomfort caused by clinical HAE symptoms that makes it impossible to perform daily activities.

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.

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Very common and common side effects

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

NOTE: This is not a complete list of side effects; for a complete list please refer to part III of the Berinert® Product Monograph.

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

[†] 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 AE.

For more information and a complete risk/benefit profile, please contact your Healthcare Professional or Customer Service at 1-866-773-7721 ext. 2386 or refer to the Product Monograph available on our website at www.cslbehring.ca.

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:

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:

EMERGENCY PROCEDURES Continued

Emergency Wallet Cards

https://www.allabouthae.ca/docs/HA_E_WalletCard.pdf

Emergency Management of Hereditary Angioedema (HAE)

PATIENT IDENTIFICATION

Name: _____
Date of Birth: _____
Health System #: _____

PROMPT TREATMENT REQUIRED TO PREVENT RAPID DETERIORATION

Supported by the Canadian Hereditary Angioedema Network (CHAEN) / Réseau Canadien d'Angioedème Héritaire (RCAEH) (www.haenetwork.com)

DIAGNOSIS

HAE is a rare potentially life-threatening disease usually caused by C1-esterase inhibitor deficiency associated with tissue swelling (see description on back page of this wallet card)

PROMPT TRIAGE & ASSESSMENT:

To determine the severity of the swelling.

PROMPT TREATMENT:

Will rapidly instate onset or relief of the angioedema in this patient and decrease morbidity.

AIRWAY OBSTRUCTION:

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

RECOMMENDED TREATMENT

C1-INH (IV): 20 U/kg. Antidote: $\frac{1}{2}$ of total _____ of C1-INH 500 units (available at Blood Bank)

Other: _____

If above not available, consider solvent detergent treated plasma (SDPP) or low sulfate fresh frozen plasma (LFFP).

Angioedema attacks usually do not respond to treatment with glucocorticoids, antibiotics or epinephrine.

This patient may require prophylaxis before surgery or dental procedures in order to prevent an angioedema attack.

CLINICAL CHARACTERISTICS OF HAE

Recurrent non-painful edema of skin and submucosal tissue associated with pain, nausea, vomiting, diarrhea, and life-threatening airway swelling*.

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

Supported by: HAE Canada by the Hereditary Angioedema Patient organization (www.haenetwork.com)

HAE AEA
CRITICAL CARE

HEALTHCARE TEAM

In case of Emergency, Contact my Physician:

MD / specialty: _____
Hospital: _____

Other Clinic / Physicians

MD / specialty: _____
Hospital: _____

Physician signature: _____
Date of Recommendation: / /
Day / Month / Year

EMERGENCY CONTACTS

Please Contact:

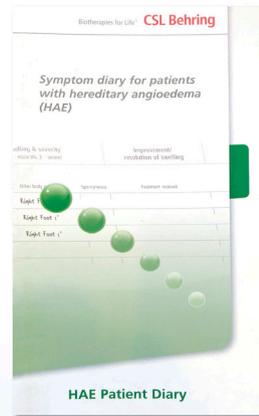
Name: _____
Relationship: _____

Other Recommendations / comments: _____

References:
1. Consensus and Evidence for Emergency Treatment
www.haenetwork.com/files/2016/06/20160620_HAE_Emergency_Treatment.pdf
2. Consensus and Evidence for Prophylaxis
www.haenetwork.com/files/2016/06/20160620_HAE_Prophylaxis.pdf

RESOURCES

Patient Diary



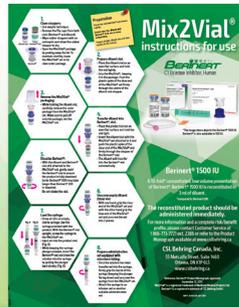
HAE Patient Diary

RESOURCES

Mix2Vial® resources



Mix2Vial® instructions sheet



RESOURCES

Web site:
allabouthae.ca

Links to the HAE community*



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

Additional Berinert® Information

For more information and a complete risk/benefit profile, please contact Customer Service at 1-866-773-7721 ext. 2386 or refer to the Product Monograph available on our website at <http://labeling.cslbehring.ca/PM/CA/Berinert/EN/Berinert-Product-Monograph.pdf>

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1. Best Practices for Environmental Cleaning for Prevention and Control of Infections in AllHealth Care Settings, 3rd Edition. April 2018. Provincial Infectious Diseases Advisory Committee. Public Health Ontario. Available at: <https://www.publichealthontario.ca/-/media/documents/bp-environmental-cleaning.pdf>. Accessed April 23, 2020.

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 Mix2Vial® is a registered trademark of West Pharma. Services IL, Ltd.

