BERINERT® (C1 Esterase Inhibitor [Human])

ADMINISTRATION SUPPLIES

REQUIRED & INCLUDED

- BERINERT in a single-dose vial [NDC 63833-835-01]
- 10 mL vial of Sterile Water for Injection, USP [NDC 63833-765-15]
- 10 mL silicone-free syringe
- 25G x 3/4 Intravenous butterfly needle set
- Mix2Vial filter transfer set
- Alcohol swabs

SUGGESTED ADDITIONAL SUPPLIES

- Tourniquet*
- Tape or transparent dressing*
- Bandage (adhesive dressing)*
- Sharps container*
- Gloves (if recommended by the healthcare provider)*
- Treatment diary or log book*

*Not supplied by CSL Behring with BERINERT

ADMINISTRATION

- Intravenous use only.
- Administer BERINERT by slow intravenous injection at a rate of approximately 4 mL per minute (dose of 20 International Units (IU) per kg body weight).
- Reconstitute BERINERT prior to use using the Sterile Water for Injection, USP provided.
- Administer at room temperature within 8 hours of reconstitution.
- Do not mix BERINERT with other medicinal products. Administer BERINERT by a separate infusion line.
- Use aseptic technique when administering BERINERT.
- Use the silicone-free syringe provided in the administration kit.
- After administration, immediately discard any unused product and all used disposable supplies in accordance with local requirements.
- Appropriately trained patients may self-administer upon recognition of an HAE attack.

HOW SUPPLIED

BERINERT is suppled in a single-dose vial together with an administration kit

Table 1. How Supplied

	Carton NDC Number	Components
500 IU	63833-825-02	• BERINERT in a single-dose vial [NDC 63833-835-01] • 10 mL vial of Sterile Water for Injection, USP [NDC 63833-765-15] • 10 mL silicone-free syringe • IV set and butterfly needle (25G x 3/4) • Mix2Vial filter transfer set • Alcohol swabs

The material provided is for informational purposes only. CSL Behring does not endorse specific devices, needles, or supplies and is not responsible for any omissions or accuracy of the product information. This may not be a complete list of vendors that supply the products below. The product manufacturer should be contacted for information and questions regarding their specific ancillary supplies. The products listed in the following tables have not been tested by CSL Behring.

BERINERT C1 Esterase Inhibitor, Human On-Demand Treatment

A 10 mL silicone-free syringe manufactured by B.Braun Medical, Inc. is provided in the BERINERT administration kit.[1]

Silicone-Free Syringes*

Table 1. Manufacturers of Silicone-Free Syringes

Product Name	Manufacturer	Contact
INJEKT Syringe	B.Braun Medical, Inc.	1 800-523-9676
NORM-JECT® Syringes	Air-Tite Product Company, Inc	1-866-929-2655
Daikyo Crystal Zenith® Luer Lock Syringe Systems	West Pharmaceutical Services	1-800-345-9800
HSW Norm-Ject® Luer Lock Syringes	Thomas Scientific	1-800-345-2100

A SURFLO® 25G x ¾ winged infusion set manufactured by Terumo Medical Products is provided in the BERINERT administration kit.[2]

IV set and butterfly needle *

Table 2. Manufacturers of Intravenous Butterfly Needle Sets

Product Name	Manufacturer	Contact
Infusion Set McKesson Prevent®	McKesson	1-855-571-2100
SURFLO® Winged Infusion Sets	Terumo Medical Products	1-800-888-3786
SURFLO® Winged Infusion Sets	Exel	1-310-649-0707

If you have a medical information question, please call 1-800-504-5434 or email the Medical Information Mailbox at MedinfoNA@cslbehring.com.

Trademarks of ancillary supplies are the property of their respective owners. *Not an all-inclusive list

1. DOF.BRN.Silicone.Free.Syringe.Administration.Kit
2. DOF.BRN.Size.Gauge.Needle

Important Safety Information

BERINERT is a plasma-derived concentrate of C1 Esterase Inhibitor (Human), indicated for the treatment of acute abdominal, facial or laryngeal attacks of hereditary angioedema (HAE) in adult and pediatric patients. The safety and efficacy of BERINERT for prophylactic therapy have not been established.

Monitor patients for early signs of allergic or hypersensitivity reactions (including hives, generalized urticaria, chest tightness, wheezing, hypotension, and anaphylaxis). If hypersensitivity is suspected, immediately discontinue administration of BERINERT and initiate appropriate treatment. Epinephrine should be immediately available for treatment of acute severe hypersensitivity reactions.

The most serious adverse reaction reported in subjects who received BERINERT in clinical studies was an increase in severity of pain associated with HAE. Dysgeusia was the most common adverse reaction reported in over 4% of subjects and more frequently than in the placebo group.

Please see full prescribing information for BERINERT, including the patient product information.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch