

Executive Summary



Reinforce HAEGARDA® as routine prophylaxis to prevent attacks for all Hereditary Angioedema (HAE) patients as first-line therapy based on its proven efficacy delivered through a well-established mechanism of action (C1-INH).

<https://www.haegarda.com/>



Continue to reinforce the need to be prepared with a highly effective rescue medication and highlight the BERINERT® proven efficacy delivered through a well-established mechanism of action (C1-INH).

<https://www.berinert.com/>



The Superior* Solution for warfarin reversal with Fast and Sustained Hemostasis.

<https://www.kcentra.com/>

*In 2 head-to-head trials, KCENTRA® demonstrated superiority to plasma in 3 of 4 efficacy endpoints.

This executive summary is meant as an introduction to the products. It is not a substitute for training on promotional claims.

Hereditary Angioedema (HAE)

HAEGARDA is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent HAE attacks in patients 6 years of age and older. HAEGARDA is for subcutaneous use after reconstitution.

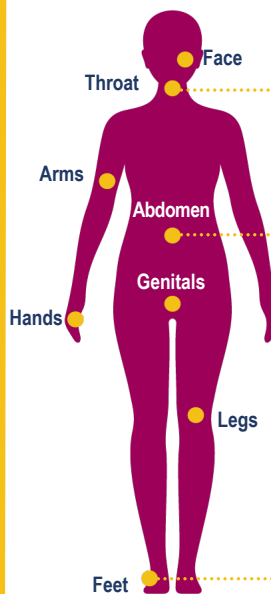
BERINERT is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal HAE attacks in adult and pediatric patients. The safety and efficacy of BERINERT for prophylactic therapy have not been established.

What Is HAE?

People with HAE are missing or have low levels of the protein C1-INH or, their C1-INH levels are sufficient but the protein does not function properly.

When there is an insufficient amount of working C1-INH, blood vessels and capillaries in the body can become leaky and allow fluid to build up in the surrounding areas. This leads to the swelling and the pain experienced during an attack.

Symptoms of HAE



Swelling of the throat is a less common type of attack but about 50% of the HAE population has had one

70% to >90% of patients experience abdominal pain caused by swelling of the gastrointestinal wall

Skin swelling most commonly affects the upper extremities vs lower extremities, followed by the face and genitals

There are 3 types of HAE:

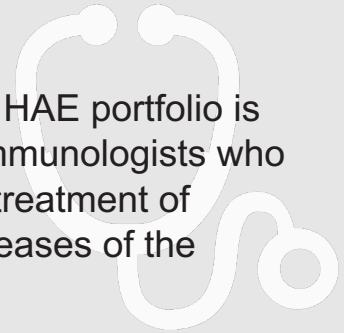
- ~85% of patients have type I HAE, in which the body does not produce enough C1-INH
- ~15% of patients have type II HAE, in which the body produces C1-INH that does not function correctly
- HAE very rarely occurs in patients with normal C1-INH levels and/or function; HAEGARDA and BERINERT are not indicated to treat this type of HAE

HAEGARDA for HAE



The Customer

Education and promotion of the HAE portfolio is primarily directed to allergists/immunologists who specialize in the diagnosis and treatment of allergies, asthma, and other diseases of the immune system, including HAE.



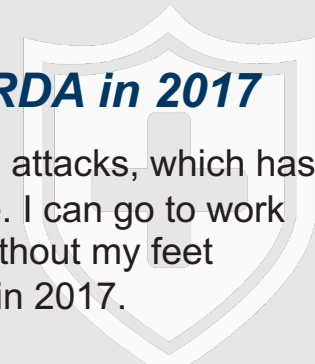
Patient Story

Alexa, started HAEGARDA in 2017

“HAEGARDA prevents my HAE attacks, which has made my life more manageable. I can go to work and walk 10,000 steps a day without my feet swelling.” Started HAEGARDA in 2017.

View more of Alexa’s story at:

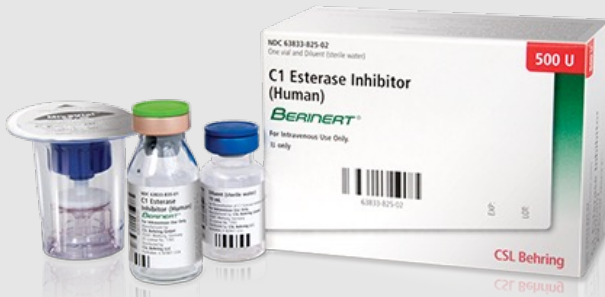
<https://www.haegarda.com/patient-testimonial>



Competitors (HAEGARDA)

| Routine prevention of HAE | Mechanism of action | Indicated population |
|---------------------------|---|---------------------------|
| Cinryze® | C1 esterase inhibitor | Patients ≥6 years of age |
| Orladeyo™ | Plasma kallikrein inhibitor | Patients ≥12 years of age |
| Takhzyro® | Plasma kallikrein inhibitor (monoclonal antibody) | Patients ≥12 years of age |

BERINERT for HAE



BERINERT is a self- or caregiver-administered, on-demand treatment for patients with HAE. BERINERT is administered by IV injection, enabling it to work quickly* to restore the body's ability to stop the swelling.

The recommended BERINERT dosage is 20 international units (IU) per kilogram body weight, with a recommended infusion rate of 4 mL/minute. For example, a 70-kg patient would require 1400 IU, infused over 7 minutes.

*Median time to complete resolution of HAE symptoms was 4.9 hours in a phase 3 clinical trial and 8.4 hours in an open label extension.

BERINERT can be self-administered at home or anywhere that's convenient. In fact, a study showed that **95% of BERINERT infusions were administered at home or in other nonhealthcare settings.**

Competitors (BERINERT)

| Acute HAE attacks | Mechanism of action | Indicated patient population |
|-----------------------|---|------------------------------|
| Firazyr® and generics | Bradykinin B2 receptor antagonist | Adults ≥18 years of age |
| Kalbitor® | Plasma kallikrein inhibitor | Patients ≥12 years of age |
| Ruconest® | Plasma-free recombinant C1-esterase inhibitor concentrate | Adults and adolescents |

KCENTRA for Urgent Warfarin Reversal

KCENTRA, Prothrombin Complex Concentrate (Human), is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA—eg, warfarin) therapy in adult patients with acute major bleeding or the need for an urgent surgery/invasive procedure. KCENTRA is for intravenous use only.

Patient Case Study* *Susan, 62 years**



*Hypothetical patient

Medical history

- Atrial fibrillation
- Hypertension
- Diabetes mellitus
- Chronic kidney disease
- Congestive heart failure

Current medications

- Warfarin 7.5 mg once daily
- Hydralazine
- Insulin
- Atorvastatin
- Lisinopril

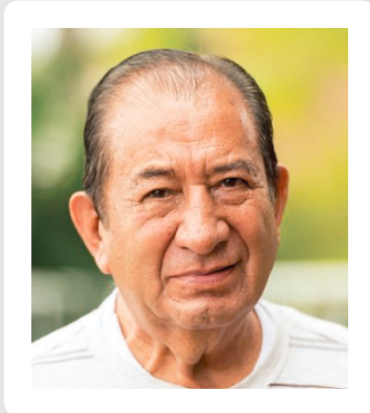
At Risk for Fluid Overload

Susan, 62,* was transported to the emergency department after her family found her lying on the bathroom floor. In the emergency department, Susan was diagnosed with an intracranial hemorrhage. She received medication to stabilize her and control her blood pressure. Additionally, for reversal of warfarin, Susan received KCENTRA 25 units/kg x 72 kg (1800 units) along with a vitamin K 10-mg intravenous (IV) infusion. Susan's international normalized ratio (INR) was normalized to 1.1 within 30 minutes and 24 hours later it was still 1.1. Subsequently, she was discharged to a rehabilitation facility.

To see the full patient case study, visit <https://labeling.cslbehring.com/PRODUCT-DOCUMENT/US/Kcentra/EN/Kcentra-Intracranial-Hemorrhage.pdf>

KCENTRA for Urgent Warfarin Reversal

Patient Case Study* *William, 72**



Medical history

- Aortic valvular disease
- Hypertension
- Chronic kidney disease
- Congestive heart failure

Current medications

- Warfarin 5 mg once daily
- Beta-adrenergic receptor blocker
- Angiotensin-converting enzyme (ACE) inhibitor

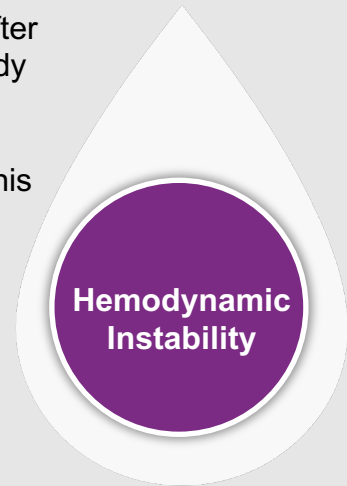
At Risk for Fluid Overload

William, 72,* was taken to the emergency department by his wife after 3 days of gastrointestinal (GI) pain with nausea, vomiting, and bloody stools. Based on examination and imaging results, William was diagnosed with an upper GI bleed as a complication of warfarin treatment. His heart rate was elevated (135 beats per minute) and his blood pressure was low (90/60 mm Hg), indicative of hemodynamic instability. Hemoglobin (7.4 g/dL) and hematocrit (21.2%) were also below normal levels and INR was 3.4. William was admitted to the intensive care unit (ICU). For reversal of warfarin, William was administered KCENTRA 25 units/kg x 110 kg (2500 units) along with a vitamin K 10 mg IV infusion. His INR was normalized to 1.2 within 30 minutes and 24 hours later, was 1.3. Following cauterization, there was a complete cessation of bleeding.

To see the full patient case study, visit

<https://labeling.cslbehring.com/PRODUCT-DOCUMENT/US/Kcentra/EN/Kcentra-Gastrointestinal-Bleed.pdf>

*Hypothetical patient





Specialty Portfolio

KCENTRA for Urgent Warfarin Reversal

KCENTRA® Customers



The **emergency department** provides immediate/urgent medical and surgical care. Key contacts include RN educator, RN manager, ER pharmacist, ER MDs, trauma MDs, ED medical director.

The **pharmacy** is a key department in the hospital. Pharmacists prepare medications, give pharmacologic information to the multidisciplinary health care team, and review and interpret physician orders.

The **director of stroke** leads a team that provides resuscitation, stabilization, assessment, and initiates treatment or makes decisions to transfer patients for treatment.

ICU/CCUs provide care to patients with severe or life-threatening illnesses and injuries, including major gastrointestinal (GI) bleeds patients.

Hospitalists work exclusively in the hospital, treating only hospital inpatients.

RNs/administrative staff can assist with scheduling in-services, scheduling meetings with director and ED physicians, and aid in recruitment for KCENTRA programs via invitation to ED staff.

Surgery

Acute care surgery encompasses trauma, critical care, and emergency surgery. Key contacts include neurosurgeons and GI surgeons.

The **trauma team** is a multidisciplinary group of individuals drawn from specialties in emergency medicine, intensive care, surgery, nursing, allied health and support staff, who work together as a team to assess and manage a trauma patient.

Neurosurgeons have the expertise to perform complex surgical procedures to treat a range of traumatic injuries (brain and spine).

GI surgeons treat diseases of the parts of the body involved in digestion. Area of surgery would include the upper and lower GI.

Competitor (KCENTRA)

Fresh frozen plasma (FFP)

