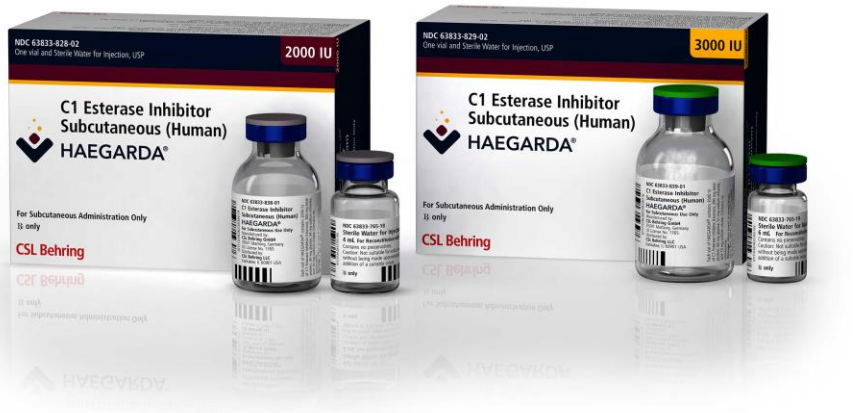
Haegarda (C1 esterase inhibitor)



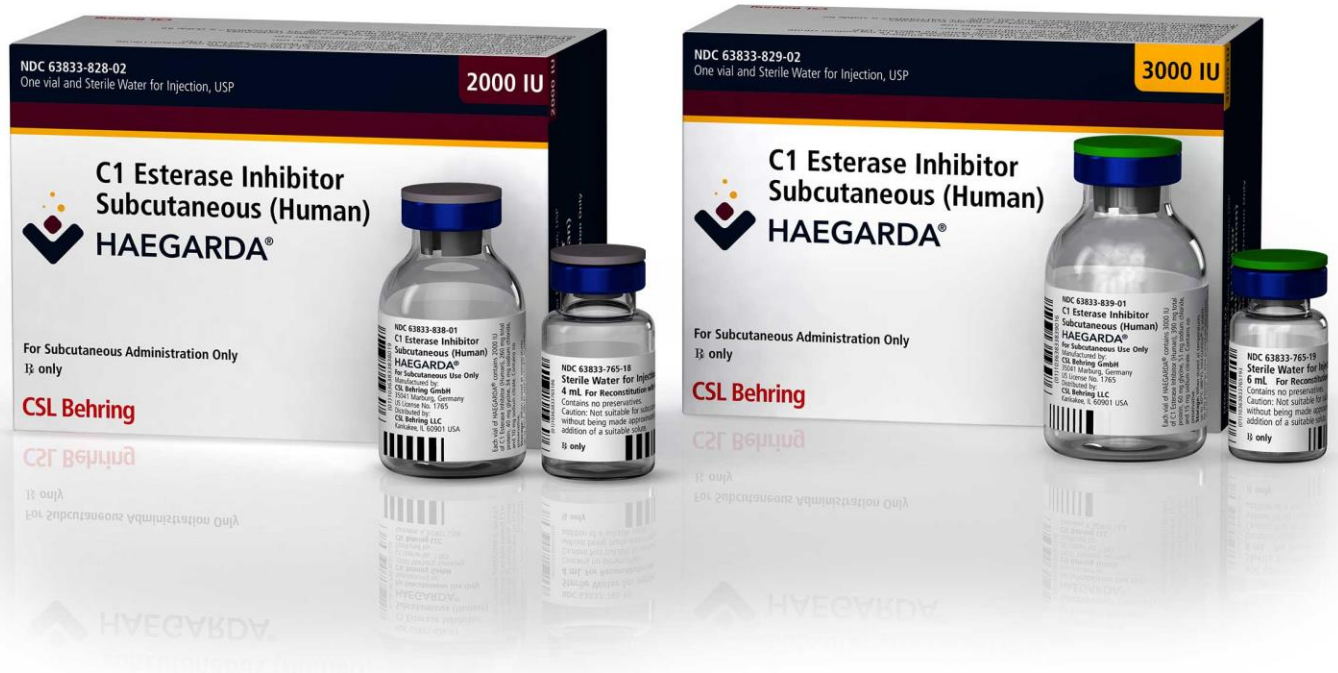
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Haegarda
- **Generic name:** C1 esterase inhibitor (human)
- **Pharmacological class:** C1 inhibitor
- **Strength and Formulation:** 2000 IU, 3000 IU; lyophilized pwd for SC inj after reconstitution
- **Manufacturer:** CSL Behring
- **How supplied:** Single-use vial—1
- **Legal Classification:** Rx

HAEGARDA


NDC 63833-828-02
One vial and Sterile Water for Injection, USP
2000 IU
C1 Esterase Inhibitor
Subcutaneous (Human)
HAEGARDA®
For Subcutaneous Administration Only
℞ only
CSL Behring
NDC 63833-829-02
One vial and Sterile Water for Injection, USP
3000 IU
C1 Esterase Inhibitor
Subcutaneous (Human)
HAEGARDA®
For Subcutaneous Administration Only
℞ only
CSL Behring

Indications

- Routine prophylaxis to prevent **hereditary angioedema (HAE) attacks** in adolescent and adult patients

Dosage & Administration

- Rotate injection sites
- Give by SC injection (eg, abdominal area, other SC sites)
- 60 IU/kg twice weekly (every 3 or 4 days)

Considerations for Special Populations

- **Pregnancy:** No prospective data in pregnant women
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** No overall differences in safety or efficacy were observed
- **Elderly:** No overall differences in safety or efficacy were observed

Warnings/Precautions

- **Discontinue** and treat if severe hypersensitivity reactions occur
- Have epinephrine injection available
- Risk of **thromboembolism events**
- Contains human plasma; monitor for possible **infection transmission** (eg, viruses, Creutzfeldt-Jakob disease agent)

Adverse Reactions

- Injection site reaction
- Hypersensitivity
- Nasopharyngitis
- Dizziness

Mechanism of Action

- C1-INH is a normal constituent of human plasma and belongs to the group of serine protease inhibitors that includes antithrombin III, alpha1-protease inhibitor, alpha2-antiplasmin and heparin cofactor II

Mechanism of Action

- C1-INH has an important inhibiting potential on major human cascade systems, including the complement, fibrinolytic and coagulation systems
- C1-INH is the main inhibitor for coagulation factor XIa of the intrinsic coagulation cascade

Clinical Studies

- Haegarda was evaluated in a multicenter, randomized, double-blind, placebo-controlled, crossover study of patients with symptomatic HAE type I or II (n=90)
- Patients were randomized to receive either Haegarda 60 IU/kg or 40 IU/kg in a 16-week period and placebo in the other 16-week period

Clinical Studies

- Efficacy was determined by the time-normalized **number of HAE attacks** (the rate of attacks) in the last 14 weeks of each treatment period

Clinical Studies

- The time normalized number of HAE attacks with 60 IU/kg was **0.52** attacks per month vs. **4.03** attacks per month with placebo (*P*<0.001)

- The time normalized number of HAE attacks with 40 IU/kg was **1.19** attacks per month vs. **3.61** attacks per month with placebo (*P*<0.001)

Clinical Studies

- The median percentage reduction in the time-normalized number of HAE attacks relative to placebo was **95%** with 60 IU/kg and **89%** with 40 IU/kg

- The percentage of responders with a **≥50% reduction** in the time-normalized number of HAE attacks with Haegarda vs. placebo was 83% (95% CI: 73, 90)

Clinical Studies

- Haegarda also resulted in a significant difference in the rate of rescue medication use vs. placebo
  - 60 IU/kg vs. placebo: 0.3 vs. 3.9 uses per month
  - 40 IU/kg vs. placebo: 1.1 vs. 5.6 uses per month
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/haegarda/drug/34718/