

Your Guide to HAEGARDA®



HAEGARDA®
C1 Esterase Inhibitor
Subcutaneous (Human)

Learning about HAE and HAEGARDA®

What is HAE?

Hereditary angioedema (HAE) is a rare genetic condition affecting approximately 1 in 10,000 to 1 in 50,000 people.



HAE causes painful unpredictable swelling (edema) attacks in different parts of the body and can affect the face, tongue, larynx, hands, arms, feet, legs, genitals, upper airway, and bowels (intestines).



Depending on the type of HAE you have, C1 esterase inhibitor (C1-INH) is either lacking or does not work properly. C1-INH is naturally produced by the body and helps regulate the systems important to your health, such as the immune and coagulation (blood clotting) systems. When you are low on working C1-INH, these systems may not work properly and thus cause swelling associated with HAE.



What is HAEGARDA® used for?

HAEGARDA® is an injectable medicine used to prevent swelling and/or painful attacks in adults and adolescents with HAE.

HAEGARDA® should not be used to treat an acute HAE attack.
In the event of an acute attack, seek medical attention.

How does HAEGARDA® work?

HAEGARDA® contains C1-INH which replaces the missing or malfunctioning C1-INH protein needed to prevent HAE swelling symptoms.

If you have any questions about HAE or HAEGARDA®, talk to your healthcare professional.

• C1-INH ↓



In untreated HAE, C1-INH is either lacking or does not work properly

• C1-INH ↑



HAEGARDA® adds C1-INH to your body

How is HAEGARDA® supplied?

HAEGARDA® is supplied as a white lyophilized powder in the following two dosage formats:



2000 IU:

Contains 2000 IU of C1-INH per injection vial accompanied with 4 mL diluent (Sterile Water for Injection) for reconstitution



3000 IU:

Contains 3000 IU of C1-INH per injection vial accompanied with 6 mL diluent (Sterile Water for Injection) for reconstitution

For both HAEGARDA® dosage formats after reconstitution, the concentration is 500 IU/mL

What is included in the HAEGARDA® package?

The product package includes:

1 vial with
HAEGARDA® powder



1 vial of diluent
(Sterile Water for
Injection)



1 Mix2Vial®
transfer device for
reconstitution



The inner carton contains:

1 syringe (10 mL)
for withdrawal



1 subcutaneous
(SC) infusion set



1 hypodermic needle



The components used in the packaging for HAEGARDA® are latex-free



 **HAEGARDA[®]**
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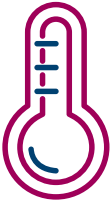


**HOW DO I STORE
HAEGARDA[®]?**

Storing HAEGARDA® before reconstitution

- Keep the non-reconstituted HAEGARDA® in its original carton to protect from light until ready to use
- The shelf life of HAEGARDA® is 36 months
- When stored in the refrigerator or at room temperature (at +2°C to +30°C), HAEGARDA® is stable for the period indicated by the expiration date on its label
- Do not freeze

Storing HAEGARDA® after reconstitution



If the reconstituted product is not administered immediately, storage should not be more than 8 hours at room temperature.



For reconstitution instructions, please see HAEGARDA® Patient Medication Information and talk to your healthcare professional.



The reconstituted product should only be stored in the vial.



Do not freeze the reconstituted solution.

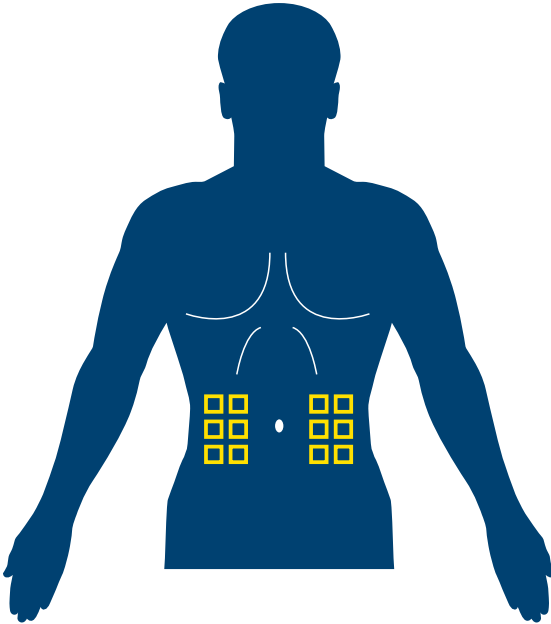
Keep out of reach and sight of children

Dosing and preparation of HAEGARDA®



What is the usual HAEGARDA® dose?

- The recommended usual dose is **60 IU per kg** of body weight twice a week (every 3 or 4 days) given after reconstitution by subcutaneous (under the skin) injection at a rate that you are able to tolerate



HAEGARDA® is administered subcutaneously in the abdominal area or other injection sites.

How do I prepare HAEGARDA® at home?

You should prepare the prescribed dose of HAEGARDA® for self-administration as directed by your healthcare professional.

- **Do not attempt to self-administer unless you have been taught how by your healthcare professional**
- Your healthcare professional will prescribe the dose that you should administer, which is based on your body weight
- Talk to your healthcare professional before traveling to make sure you have an adequate supply of HAEGARDA®
- Use a new needle for each HAEGARDA® injection

For home treatment and self-administration instructions, please see HAEGARDA® Patient Medication Information and talk to your healthcare professional

When is the best time to inject HAEGARDA®?

Because you take HAEGARDA® yourself, you and your healthcare provider can determine the appropriate time and place to administer.

What if I overdose?

- No cases of overdose have been reported. **If you think you have taken too much HAEGARDA®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if you have no symptoms.**

What if I miss a dose?

- If you miss a dose, proceed with your next dose immediately and continue at regular intervals as advised by your healthcare professional. Do not take a double dose to make up for a forgotten dose.

What are the warnings and precautions?

Do not use HAEGARDA® if:

- You have experienced life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product

Talk to your healthcare provider if there are any concerns, health conditions or problems you may have, including the following:



You are pregnant or planning to become pregnant. The effect of HAEGARDA® on your unborn baby is not known.



You are breastfeeding or plan to breastfeed. It is not known if HAEGARDA® passes into your breast milk or if it can affect your baby.



You have a history of blood clotting problems. Blood clots have occurred in patients receiving HAEGARDA®. Very high doses of C1-INH could increase the risk of blood clots.

Tell your healthcare professional:

- If you have a history of heart or blood vessel disease, stroke, blood clots, or have thick blood, an indwelling catheter/access device in one of your veins, or have been immobile for some time. These factors may increase your risk of having a blood clot after using HAEGARDA®
- What drugs you are using, as some drugs, such as birth control pills or certain androgens, may increase your risk of developing a blood clot

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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

Appropriate vaccination (hepatitis A and B) should be generally considered for subjects in regular/repeated receipt of human plasma-derived products.



What are the possible side effects from using HAEGARDA®?

Allergic reactions may occur with HAEGARDA®. Talk to your healthcare professional right away if you have any of the following symptoms after using HAEGARDA®:

- Wheezing
- Difficulty breathing
- Chest tightness
- Turning blue (look at lips and gums)
- Fast heartbeat
- Swelling of the face
- Rash or hives

Signs of a blood clot include:

- Pain and/or swelling of an arm or leg with warmth over the affected area
- Discoloration of an arm or leg
- Unexplained shortness of breath
- Unexplained rapid pulse
- Chest pain or discomfort that worsens on deep breathing
- Numbness or weakness on one side of the body

The most common side effects with HAEGARDA® are injection site reactions (pain, redness, swelling), hypersensitivity (itching and rash), nasopharyngitis (runny or stuffy nose, sneezing, watery eyes) and dizziness.

These are not all the possible side effects that you may experience when taking HAEGARDA®

For general information about HAE and support, please visit these websites:

- Canadian Hereditary Angioedema Network (CHAEN) <https://chaen-rcah.ca/>
- HAE Canada Patient Organization www.haecanada.org
- L'angio-oedème héréditaire du Québec (AOHQ) <https://www.aohq.ca/en/>
- You may also use the HAERO app to track and record your treatments



**Download the
HAERO App**

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