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?

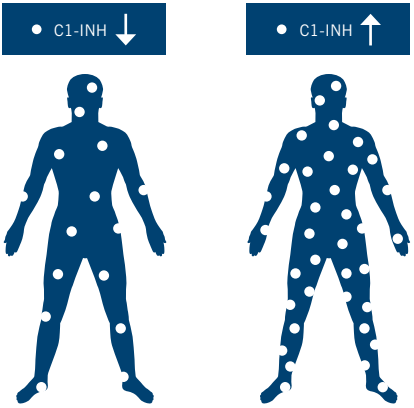
HAEGARDA is an injectable medicine used to prevent swelling and/or painful attacks in adults and adolescents with HAE.

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 human C1-INH that replaces the missing or defective C1-INH protein made by the body to prevent HAE swelling symptoms.

If you have any questions about HAE or HAEGARDA, talk to your healthcare professional. You can also visit patients.cslbehring.ca for more information.



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

HAEGARDA adds C1-INH to your body.

HAE=hereditary angioedema; C1-INH=C1 esterase inhibitor.

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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 5.6 mL diluent (Sterile Water for Injection) for reconstitution.

For both HAEGARDA dosage formats after reconstitution, the concentration is 500 IU/ML.

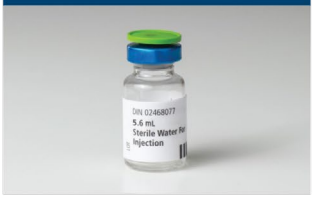
C1-INH=C1 esterase inhibitor.

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 includes:

1 syringe (10 mL) for withdrawal

1 subcutaneous (SC) infusion set

1 hypodermic needle

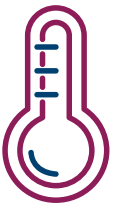
The components used in the packaging for HAEGARDA are latex-free.

How do I store HAEGARDA®?

Storing HAEGARDA® before reconstitution?

- Keep in its original carton to protect from light until ready to use.
- The shelf life of HAEGARDA is 36 months.
- Store 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 it is not administered immediately, do not store beyond 8 hours at room temperature.

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

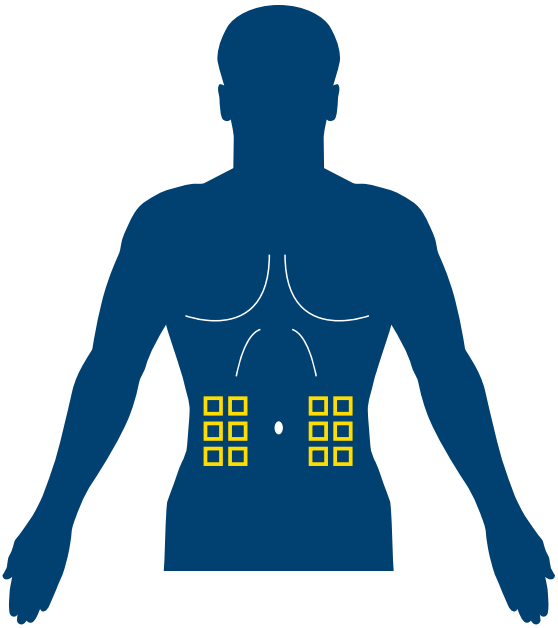
Only store the reconstituted product in the vial.

Do not freeze the reconstituted product.

Keep out of reach and sight of children.

What is the usual HAEGARDA dose?

- The recommended usual dose is 60 IU/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 as discussed with a healthcare professional.

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 travelling 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 your HAEGARDA Patient Medication Information Leaflet and talk to your healthcare professional.

When is the best time to inject HAEGARDA?

Because you take HAEGARDA yourself, you and your healthcare professional 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 professional 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 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 or blood clots, have thick blood or 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 (e.g., 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 an/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 (inching 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.

Talk to your healthcare professional if you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities.

CSL PLUS*

A program designed to facilitate your treatment journey with HAEGARDA®

Step 1 Enrolment

After you have been prescribed HAEGARDA and you have been enrolled into the CSL PLUS program by your healthcare professional, a Nurse Case Manager will call you to:

- Explain the program.
- Describe the services and set up training.
- Ask you questions about your medical history.
- Provide information about your treatment.

Step 2 Obtaining HAEGARDA

Once you are ready to begin your training:

- Your Nurse Case Manager will coordinate your HAEGARDA pick-up with the blood bank. A blood bank is a department within the hospital that stores and distributes HAEGARDA.
- Telephone: _____
- Location: _____
- Pick-up instructions: _____

_____

_____

Step 3 Training and Ongoing Nurse Support

From the moment you enrol with CSL PLUS, our program team will provide you with:

- Information on HAEGARDA.
- Unlimited one-on-one training to help you learn to administer HAEGARDA at the clinic or in the comfort of your home.
- Ongoing support, education and training throughout the course of your therapy.

Step 4 Reports to Physician

Our program team will send:

- Reports to the blood bank when you are trained.
- Summary notes for your physician at every touchpoint.

While there is a standard schedule, our program team can customize the schedule based on your individual needs.

If you have any questions at any time about HAEGARDA or the CSL PLUS program, please email **support@cslplus.ca** or speak with your Nurse Case Manager by calling **1-888-490-4105, Monday to Friday from 8 AM – 8 PM EST.** Alternatively, you can contact your healthcare professional.

* If you have not been enrolled in the CSL PLUS program, please contact your healthcare professional for more information.

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For general information about HAE and support

- Canadian Hereditary Angiodema 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

HAERO

App Store

Google Play

Download the HAERO App to track and record your treatments

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