CSL Behring

HAEGARDA®

SELF-ADMINISTRATION GUIDE

STEP-BY-STEP INSTRUCTIONS FOR PREPARING AND ADMINISTERING HAEGARDA®

Use this guide in conjunction with Patient Medication Information of the Product Monograph and training provided by a healthcare professional (HCP).

Do not attempt to self-administer unless you have been trained by a healthcare professional.

HAEGARDA®
C1 Esterase Inhibitor
Subcutaneous (Human)

IMPORTANT SAFETY INFORMATION

The following section describes the potential side effects associated with HAEGARDA® and precautions that should be taken when using HAEGARDA®.

IMPORTANT SAFETY INFORMATION

Home treatment/self-administration:

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.

Reconstitution and administration:

HAEGARDA® is intended for self-administration by subcutaneous injection only. The patient or caregiver should be trained on how to administer HAEGARDA®.

IMPORTANT SAFETY INFORMATION

Side effects and what to do about them

These are not all the possible side effects you may feel when taking HAEGARDA®. If you experience any side effects not listed here, contact your healthcare professional.

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

IMPORTANT SAFETY INFORMATION

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
- chest pain or discomfort that worsens on deep breathing
- unexplained rapid pulse
- 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.

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

WARNINGS AND PRECAUTIONS

Do not use HAEGARDA® if:

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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take HAEGARDA®. Talk about 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, 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®. Also, tell your healthcare professional 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.

WARNINGS AND PRECAUTIONS

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.

ABOUT THIS GUIDE

HAEGARDA® is an injectable medicine used to prevent swelling and/or painful attacks in adults and adolescents with Hereditary Angioedema (HAE). HAEGARDA® should not be used to treat an acute HAE attack. In the event of an acute attack, seek medical attention.

This self-administration guide can help you through the reconstitution and injection process, especially when you are first learning. It should be used in conjunction with training provided by a healthcare provider.

This guide is divided into 3 sections:

- Preparation and handling
- Reconstituting and administering
- Self-administration

SETTING UP A TREATMENT SCHEDULE

HAEGARDA® should be taken as prescribed by your healthcare professional. HAEGARDA® is administered by subcutaneous self-administration, so you can choose the time and place that work best for you.

Here are a few tips to help make taking HAEGARDA® part of your routine

- See the following step-by-step instructions for the reconstitution and administration of HAEGARDA®. The following steps are general guidelines for using HAEGARDA®. If you are unsure of the steps, please contact your healthcare professional before using.
- Use a new needle for each HAEGARDA® injection.
- If you miss a dose of HAEGARDA®, 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.

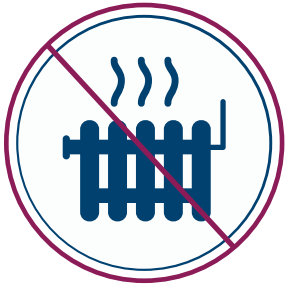
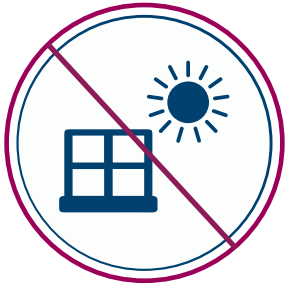
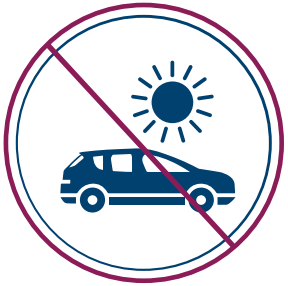
PREPARATION AND HANDLING

Instructions for setting up a clean place to reconstitute and inject HAEGARDA® with ancillaries.

PREPARATION AND HANDLING: STORING HAEGARDA®

- Store HAEGARDA® in the refrigerator or at room temperature (*at +2ºC to +30ºC*).
  Do not use the product after the expiration date.
- Keep HAEGARDA® in its original carton until ready to use. Do not freeze. Protect from light.
- Avoid extreme temperatures (outside the range indicated above).

See some examples of extreme temperatures:


>>STEP 1:

Assemble the following supplies

- HAEGARDA® and diluent vials **(Ensure that the HAEGARDA® and the diluent are at room temperature)**. Check the expiration date on the product vial label. Do not use the vial if it is beyond the expiration date.
- Mix2Vial®
- SC infusion set or hypodermic needle
- Sterile syringe
- Alcohol or disinfectant wipes
- Sharp/biohazardous container
- Treatment diary/log book
- Gloves (if recommended by your healthcare professional)

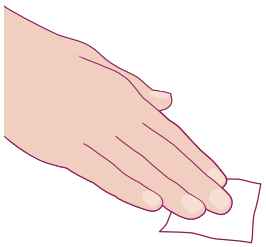
Use a new needle for every HAEGARDA® injection. Do not reuse or share needles with other people.

PREPARATION AND HANDLING

>>STEP 2:

Clean surface

Thoroughly clean a table or other flat surface using alcohol or disinfectant wipes.



>>STEP 3:

Wash hands

Thoroughly wash and dry your hands.

If you have been told to wear gloves when preparing your infusion, put the gloves on.

You can use the mat included in your HAEGARDA® Welcome Kit as a surface to prepare HAEGARDA® for self-administration. Clean the mat with an antiseptic wipe before each use.

RECONSTITUTING AND ADMINISTERING

The following are step-by-step instructions for reconstitution and administering HAEGARDA®. The steps listed below are general guidelines for using HAEGARDA®. If you are unsure of the steps, please contact your healthcare professional before using.

RECONSTITUTING AND ADMINISTERING

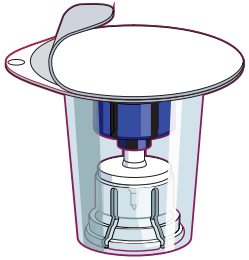
>>STEP 4:

Clean stoppers

Inspect each product vial. Check expiration date. Ensure the caps are secure. Remove the flip caps from both vials (HAEGARDA® and diluent). Wipe rubber stoppers with an antiseptic wipe and allow the rubber stopper to dry.

>>STEP 5:

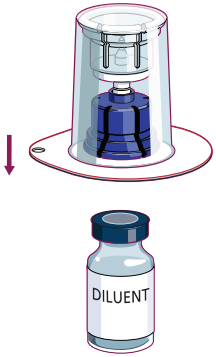
Open the Mix2Vial® package by peeling off the lid. Do not remove the Mix2Vial® from the blister package!



RECONSTITUTING AND ADMINISTERING

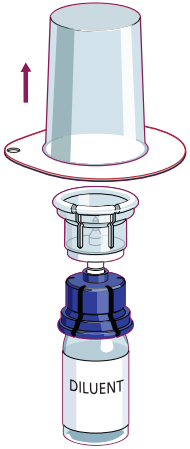
>>STEP 6:

Place the diluent vial on an even, clean surface and hold the vial tight. Take the Mix2Vial® together with the blister package and push the spike of the blue adapter end straight down through the diluent vial stopper.



>>STEP 7:

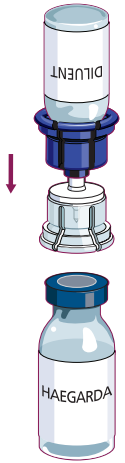
Carefully remove the blister package from the Mix2Vial® set by holding at the rim, and pulling vertically upwards. Make sure that you only pull away the blister package and not the Mix2Vial® set.



RECONSTITUTING AND ADMINISTERING

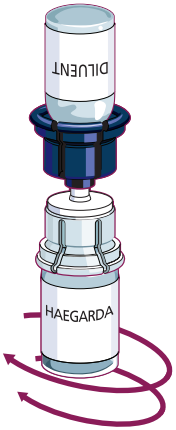
>>STEP 8:

Place the HAEGARDA® vial on an even and firm surface. Invert the diluent vial with the Mix2Vial® set attached and push the spike of the transparent adapter end straight down through the HAEGARDA® vial stopper. The diluent will automatically flow into the HAEGARDA® vial.



>>STEP 9:

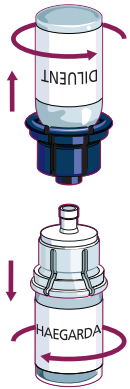
With the diluent and HAEGARDA® vial still attached to the Mix2Vial® transfer set, gently swirl the HAEGARDA® vial to ensure that the powder is fully dissolved. Do not shake the vial.



RECONSTITUTING AND ADMINISTERING

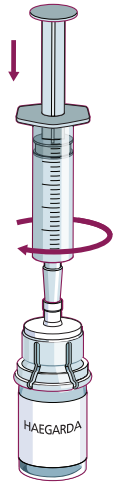
>>STEP 10:

With one hand, grasp the HAEGARDA® side of the Mix2Vial® set and with the other hand, grasp the diluent-side and unscrew the set carefully counterclockwise into two pieces. Discard the diluent vial with the blue Mix2Vial® adapter attached.



>>STEP 11:

Draw air into an empty, sterile syringe. While the HAEGARDA® vial is upright, connect the syringe to the Mix2Vial®'s Luer Lock fitting by screwing clockwise. Inject air into the HAEGARDA® vial.



RECONSTITUTING AND ADMINISTERING

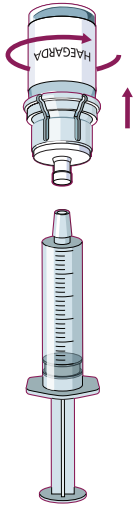
>>STEP 12:

While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.

>>STEP 13:

Now that the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the transparent Mix2Vial® adapter from the syringe by unscrewing counterclockwise. The reconstituted solution should be colourless, clear and free from visible particles.

Do not use if particulate matter or discoloration is observed.



SELF-ADMINISTRATION

The patient or caregiver should be trained on how to administer HAEGARDA®.

HAEGARDA® is intended for self-administration by subcutaneous injection only.

>>STEP 14:

Prepare injection site

- Select an area on the abdomen (stomach; Figure 1) or another subcutaneous area for the injection as discussed with a healthcare professional.
- Use a different place from your last injection.
- New injection sites should be at least 5 centimetres (2 inches) away from the place where injection was given previously.
- Never give injection in areas where the skin is itchy, swollen, painful, bruised or red.
- Avoid giving injections in places with scars or stretch marks.
- Clean the skin at the injection site with an alcohol swab and let the skin dry (Figure 2).

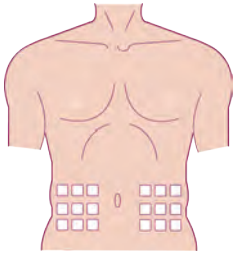


Figure 1

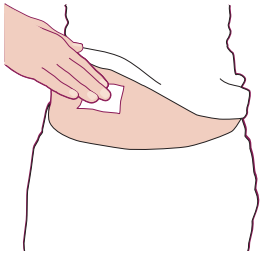


Figure 2

>>STEP 15:

Injection in the abdominal area or other subcutaneous injection area

As instructed by a healthcare provider:

- Attach a hypodermic needle or SC infusion set. Prime the needle or tubing as required and instructed.

Injection with hypodermic needle:

- Insert the needle into the fold of skin (Figure 3)

Injection by SC Infusion Set:

- Insert the needle into the fold of skin (Figure 4)

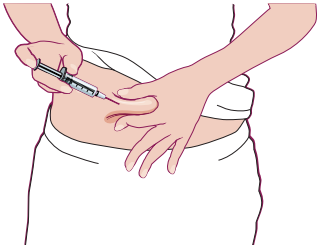


Figure 3

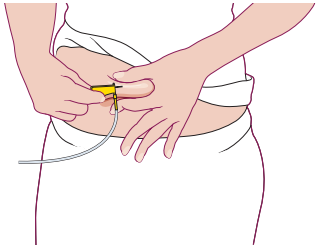


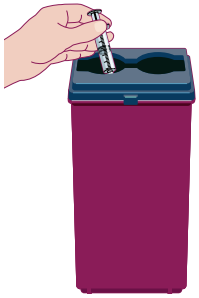
Figure 4

SELF-ADMINISTRATION

>>STEP 16:

Clean up

- After injecting the entire amount of HAEGARDA®, remove the needle.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.



>>STEP 17:

Record treatment

You may also use the HAERO app to track and record your treatments.

Download the HAERO app from the App Store or Google Play to track your attacks and treatment.

HAERO

App Store

Google Play

MORE INFORMATION

If you want more information about HAEGARDA®:
Talk to your healthcare professional

For more information and a complete risk/benefit profile, please contact Customer Service at 1-866-773-7721 ext. 2386 or refer to the Product Monograph available on our website at https://labeling.cslbehring.ca/PM/CA/Haegarda/EN/Haegarda-Product-Monograph.pdf

For patient information and resources, visit https://patients.cslbehring.ca.

HGD2024010171EN