

## TRANSFUSION MEDICINE SERVICES

<b>OTHER NAMES</b> C1-INH	<b>CLASSIFICATION</b> C1 Esterase Inhibitor	<b>ALERTS</b> Contains human plasma
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### PREPARATION and ADMINISTRATION

#### Reconstitution

Diluent: sterile water for injection  
 2000 Units/vial, reconstituted with 4 mL of diluent  
 3000 units/vial, reconstituted with 5.6 mL of diluent  
 See page 3–5 for reconstitution steps

### Subcutaneous Injection

Administer after reconstitution by subcutaneous injection at a rate tolerated by the patient.  
 HAEGARDA is administered subcutaneously in the abdominal area or other subcutaneous injection sites.

### Requirements and Monitoring

If infusion is less than 15 minutes: check vital signs before initiation (baseline), on completion, and with any development of signs/symptoms of an adverse event.

**Document all vitals taken.**

Blood pressure via cuff or arterial line  
 Temperature  
 Heart Rate  
 Respirations  
 Lung sounds in non-verbal, non-oriented or pediatric patients and patients with CHF or pulmonary dysfunction  
 Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

### INDICATIONS

Routine prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE).

### ADVERSE EFFECTS

**Adverse reactions may include:** Allergic-type hypersensitivity reactions including anaphylaxis have been reported and have manifested as pruritus, rash, urticaria, local site reactions, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue.

If an AE is suspected: stop the transfusion, disconnect and cap the blood tubing, initiate the backup line of NS and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume transfusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once transfusion is discontinued or completed.

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### DOSAGE

The recommended dose of Haegarda is 60 units/kg body weight twice weekly

The maximum tolerated dose used in patients in clinical studies was 10,000 IU, corresponding to a volume of 20 mL, twice weekly by subcutaneous injection.

### COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expire date
- Do not dilute in any IV solutions
- Protect vials from light
- Do not store unused vials in refrigerator. Administer at room temperature

### DOSAGE FORMS

- Supplied by Transfusion Medicine

### MISCELLANEOUS

- None

### RECONSTITUTION

Table 1 -

Format	Vial Size	Volume of Diluent to be Added to Vial	Concentration per mL
2000 IU	20 mL	4 mL	500 IU/mL
3000 IU	30 mL	5.6 mL	500 IU/mL


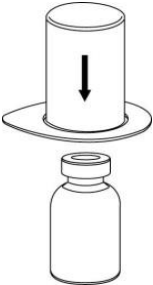

#### General Instructions:

- The reconstituted solution for HAEGARDA should be colourless and clear to slightly opalescent.
- Reconstitution is generally achieved within 5 minutes but may take as long as 10 minutes.
- After filtering/withdrawal (see below) reconstituted product should be inspected visually for particulate matter and discoloration prior to administration. Do not use solutions that have particles or deposits in them.
- Reconstitution and withdrawal must be carried out using aseptic techniques.
- The suggested infusion site for the injection of HAEGARDA is the abdominal area, however other subcutaneous injection areas can be used
- The reconstituted preparation should be administered by subcutaneous injection at a rate tolerated by the patient.

## TRANSFUSION MEDICINE SERVICES

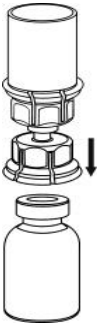


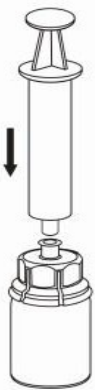
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Follow the steps below and use aseptic technique to reconstitute and administer HAEGARDA.

<p><b>Step 1: Assemble supplies</b></p> <p>Haegarda and diluent vials; Mix2Vial®; SC infusion set or hypodermic needle; sterile syringe</p>	
<p><b>Step 2: Clean surface</b></p> <p>Thoroughly clean a table or other flat surface using alcohol or disinfectant wipes.</p>	
<p><b>Step 3: Wash hands</b></p> <p>Thoroughly wash and dry your hands. Don clean gloves.</p>	
<p><b>Reconstitution:</b></p>	
<p><b>Step 4: Clean Stoppers</b></p> <p>Remove the flip caps from both vials (HAEGARDA and diluent). Wipe rubber stoppers with an antiseptic wipe and allow the rubber stopper to dry.</p>	
	<p><b>Step 5:</b> Open the Mix2Vial® package by peeling off the lid. Do not remove the Mix2Vial® from the blister package!</p>
	<p><b>Step 6:</b> 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.</p>
	<p><b>Step 7:</b> 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.</p>

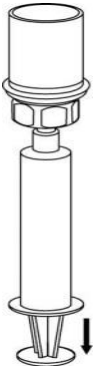

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	<p><b>Step 8:</b> Place the HAEGARDA vial on an even and firm surface. Invert the diluent vial with the Mix2Vial® set attached and push the spike of the transparent adapter end straight down through the HAEGARDA vial stopper. The diluent will automatically flow into the HAEGARDA vial.</p>
	<p><b>Step 9:</b> 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. (Generally, within 5 minutes but may take as long as 10 minutes.) Do not shake the vial.</p>
	<p><b>Step 10:</b> 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 counter-clockwise into two pieces. Discard the diluent vial with the blue Mix2Vial® adapter attached.</p>
	<p><b>Step 11:</b> 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.</p>

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	<p><b>Step 12:</b> While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.</p>
	<p><b>Step 13:</b> 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 counter-clockwise. The reconstituted solution should be colorless, clear and free from visible particles. Do not use if particulate matter or discoloration is observed.</p>

### Administration:

#### Step 14: Prepare injection site

- Select an area on the abdomen (stomach; Figure 1) or another subcutaneous area for the injection.
- Use a different place from last injection.
- New injection sites should be at least 5 centimeters (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).

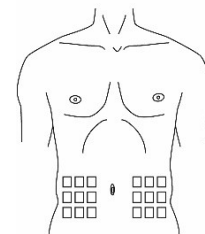


Figure 1



Figure 2

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### Step 15: Injection in the abdominal area or other subcutaneous injection area

- 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).

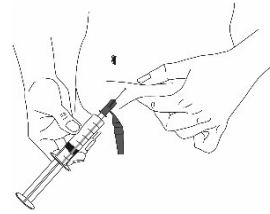


Figure 3

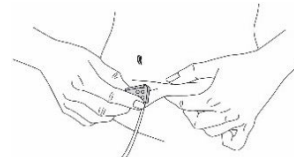


Figure 4

## REFERENCES

- [CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure](#)
- Haegarda product monograph. Found at <https://www.cslbehring.ca/products/product-list>