Class: C1 Esterase Inhibitor Subcutaneous, Human	Alternate Product Name: • HAEGARDA®	Company/Supplier: CSL Behring Canada, Inc

Routes	Intravenous			Other		
	Direct IV	Intermittent IV Infusion	Continuous Infusion	SC	IM	Other
Acceptable routes	No	No	No	Yes	No	N/A

Description	• Is a purified, pasteurised, nanofiltered, lyophilised concentrate of human C1 esterase inhibitor (C1-INH) to be reconstituted for subcutaneous (SC) administration. • It is prepared from large pools of human plasma.

Availability	• **Vial sizes/dosages:**
	  • 2000 units/vial, reconstituted with 4 mL of diluent.
	  • 3000 units/vial, reconstituted with 6 mL of diluent.
	• Supplied by Canadian Blood Services (CBS).
	• **Contact your local laboratory/transfusion laboratory service regarding in house stock availability at your site.**

Indications	• Is indicated for routine prevention of Hereditary Angioedema (HAE) attacks in adolescent and adult patients. • **Treatment should be initiated and supervised by a healthcare practitioner experienced in the use of C1 Esterase Inhibitor agents and in the management of HAE.**
Contraindications	• Contraindicated in individuals with a known allergic reaction to constituents of the preparation. • For a complete listing, see the contraindications section of product monograph https://labeling.cslbehring.ca/PM/CA/HAEGARDA/EN/HAEGARDA-Product-Monograph.pdf
Warnings	• Should not be used to treat an acute HAE attack. In case of an acute HAE attack, individualized treatment should be initiated. • Hypersensitivity reactions, including anaphylaxis, are possible. Should symptoms occur, discontinue treatment and follow adverse event protocol. See " *Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of (1141)"* • Products made from human plasma may contain infectious agents such as viruses and, theoretically, the agent responsible for the Creutzfeldt-Jakob disease (CJD) (see WARNINGS AND PRECAUTIONS AND ADVERSE EVENTS in product monograph).
Dosage	• Dosage should be determined by a physician experienced in the care of HAE patients • The recommended dose of HAEGARDA® is 60 units/kg body weight twice weekly (every 3-4 days) administered after reconstitution by subcutaneous injection at a rate tolerated by the patient. For further information about dosage please review the product monograph. • **Consult with Hematologist for safe dosing recommendations by paging through switchboard at (306) 655-1000.**

Pre-Transfusion Testing Requirements	• As directed by most responsible health practitioner (MRHP). • In addition to documentation of clinical HAE signs and symptoms, evaluation of C1 esterase inhibitor function and C4 should be obtained by the MRP to determine HAE type and management plan.
Ordering	• Specify type of concentrate and dosage required. • Off label requests must be approved by the Transfusion Medicine Medical Physician. • To request product from the transfusion medicine laboratory, use the "Plasma Protein Product Request Form" #103221.
Forms Required	• Informed Consent for Administration of Blood Components and/or Plasma Protein Products #101479. • Plasma Protein Product Request Form #103221. • Transfusion/Infusion Administration and Assessment Record #101059. • Saskatchewan Transfusion Adverse Event Report Form #103695 (only needed if adverse event occurs). • Forms can be located in the Lab Services Manual **https://www.saskatoonhealthregion.ca/locations_services/Services/Pathology-Laboratory-Med/healthpractitioners/Pages/requisitions.aspx**

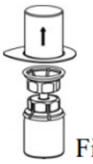
Supplies Required	• The product package includes:
	  • 1 vial with HAEGARDA® powder.
	  • 1 vial of diluent (Sterile Water for Injection).
	  • Mix2Vial® transfer device for reconstitution.
	• The inner carton contains:
	  • 1 syringe (10 mL) for withdrawal.
	  • 1 SC infusion set.
	  • 1 hypodermic needle.
	• Additional supplies needed:
	  • One luer lock syringe (appropriate size based on volume) for administration.
	  • Alcohol swab (for cleaning the tops of the vials).

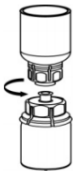
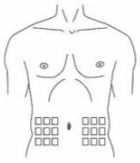
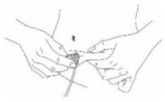
	• **Blood consent:** Is required due to human plasma component. • **Pre-infusion:** Ensure recent patient weight is on file and pertinent laboratory results are available. • Perform all other appropriate pre-transfusion checks per protocol. For Policies and Procedures of Blood Components and Plasma Protein Products - Administration of #1141. • **Administration:** ***The reconstituted preparation should be administered by subcutaneous injection at a rate tolerated by the patient.*** • For additional preparation/reconstitution and administration steps see administration section of the Product Monograph.

- **Access:** Given via subcutaneous (SC) injection.
- **Compatible Solutions:** If using SC infusion set can flush line with 0.9% normal saline following.
- **Preparation and Reconstitution**

NOTE: Storage shall not exceed 8 hours at room temperature.
The reconstituted product should only be stored in the vial.
DO NOT refrigerate or freeze the reconstituted solution.
DO NOT further dilute in any solutions.
DO NOT mix with other drugs or solutions

Use aseptic technique (clean and germ free) when preparing and reconstituting HAEGARDA®

Reconstitution:	
1. Bring the HAEGARDA® vial and diluent vial to room temperature.	
2. Place the HAEGARDA® vial, diluent vial and Mix2Vial® transfer set on a flat surface.	
3. Remove the flip caps from both vials (HAEGARDA® and diluent). Wipe rubber stoppers with an antiseptic wipe and allow the rubber stopper to dry.	
4. Open the Mix2Vial® transfer set package by peeling away the lid (Fig. 1). To maintain sterility, leave the Mix2Vial® transfer set in its clear outer package.	 Fig. 1
5. Place the diluent vial on an even flat surface and hold the vial tightly. Grip the Mix2Vial® transfer set keeping it in the clear package and push the plastic spike of the blue end of the Mix2Vial® transfer set firmly through the center of the diluent vial stopper (Fig. 2).	 Fig. 2
6. While holding the diluent vial, carefully remove the outer package from the Mix2Vial® transfer set. Make sure to pull off only the clear package, not the Mix2Vial® transfer set (Fig. 3).	 Fig. 3
7. Place the HAEGARDA® vial on an even flat surface and hold the vial tight. Invert the diluent vial with the Mix2Vial® transfer set attached to it and push the plastic spike of the clear end of the Mix2Vial® firmly through the center of the stopper of the HAEGARDA® vial (Fig. 4). The diluent will transfer into the HAEGARDA® vial automatically.	 Fig. 4
8. With the diluent and HAEGARDA® vial still attached to the Mix2Vial® transfer set, gently swirl the HAEGARDA® vial to ensure that the HAEGARDA® is fully dissolved (Fig. 5). Do not shake the vial.	 Fig. 5

	9. With one hand, grip the clear end of the Mix2Vial® transfer set and with the other hand grip the blue end of the Mix2Vial® transfer set, and unscrew counter clockwise the set into two pieces. (Fig. 6).	 Fig. 6
	10. Draw air into an empty, sterile syringe. With the HAEGARDA® vial upright, screw the syringe to the Mix2Vial® transfer set. Inject air into the HAEGARDA® vial. While keeping the syringe plunger pressed, invert the HAEGARDA® vial and draw the solution into the syringe by pulling the plunger back slowly. (Fig. 7).	 Fig. 7
	11. Once the solution has been transferred into the syringe, firmly grip the barrel of the syringe (keeping the plunger facing down) and unscrew the syringe counter clockwise from the Mix2Vial® transfer set Fig. 8). Attach the syringe to an infusion set or another suitable administration set.	 Fig. 8
	Administration:	
	12. Prepare injection site • Select an area on the abdomen (stomach; Figure 1) or another subcutaneous area for the injection as discussed with a health professional. • 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
	13. Injection in the abdominal area or other subcutaneous injection area As instructed by a health professional: • 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
	14. 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.	
	15. Record treatment Record the lot number from the HAEGARDA® vial label in the patient's treatment diary or log book with the date and time of infusion every time HAEGARDA® is used.	
	• **Lab testing post administration:** As directed by MRHP.	
Nursing Implications	• **Patient monitoring:** Follow the Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of (1141). • **Documentation:** Administration and vital signs shall be recorded on the Transfusion/Infusion Administration and Assessment Record" #101059.	
Adverse Events	• Allergic reactions are possible with administration of blood components and plasma protein products ranging from mild to life threatening. • Refer to Policies and Procedures of Blood Components and Plasma Protein Products - Administration of #1141 for managing of allergic transfusion reaction and call MRHP. • Document adverse event on Saskatchewan Transfusion Adverse Event Report Form #103695, whether or not the transfusion was discontinued.	
References	• HAEGARDA® Product Monograph, revision date of March 31, 2021. https://labeling.cslbehring.ca/PM/CA/HAEGARDA/EN/HAEGARDA-Product-Monograph.pdf Accessed on Sept 16, 2021 • Saskatoon Health Region Policies and Procedures. #1141 Blood Components and Plasma Protein Product – Administration. https://www.saskatoonhealthregion.ca/about/NursingManual/1141.pdf Accessed May 2, 2019.	