

March 11, 2021

Availability of HAEGARDA®

Dear Health Care Professional,

CSL Behring is pleased to announce that HAEGARDA® will be available through Canadian Blood Services (CBS) beginning the week of April 6, 2021.

HAEGARDA® (C1 Esterase Inhibitor Subcutaneous (Human)) is human plasma derived, purified, pasteurized, nanofiltered, lyophilized concentrate of C1 Esterase Inhibitor (C1-INH) indicated for routine prevention of Hereditary Angioedema (HAE) attacks in adolescent and adult patients, and administered subcutaneously.

HAEGARDA® is contraindicated in individuals who have experienced life-threatening hypersensitivity reactions, including anaphylaxis, to C1-INH preparations or to any ingredient in the formulation or component of the container.

As per the product monograph, the recommended dose of HAEGARDA® is 60 IU/kg body weight twice weekly (every 3-4 days) administered after reconstitution by subcutaneous injection at a rate tolerated by the patient.

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

- 2000 IU; which contains 2000 IU of C1-INH per injection vial accompanied with 4 mL of Sterile Water.
- 3000 IU; which contains 3000 IU of C1-INH per injection vial accompanied with 6 mL of Sterile Water.

The product package includes:

- 1 vial with HAEGARDA® powder
- 1 vial of diluent (Sterile Water for Injection)
- 1 Mix2Vial® transfer device for reconstitution
- 1 inner carton

The inner carton contains:

- 1 syringe (10 mL) for withdrawal
- 1 Subcutaneous infusion set
- 1 hypodermic needle

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

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 the carton and vial label.

CSL Behring Canada also provides training for the administration of HAEGARDA® via CSL Behring PLUS+ program that offers a wide array of services, and educational materials. Patients can ask their Healthcare professionals to enroll them in the program at any time.

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>

Sincerely,



Mike Leo
Director, Market Access & Government Affairs