

HAEGARDA® C1 Esterase Inhibitor Subcutaneous (Human)

TRADE NAME	HAEGARDA®
PRODUCT COMPOSITION	<p>Active Ingredient: 500 IU/mL of C1 Esterase Inhibitor</p> <p>Clinically Relevant Nonmedicinal Ingredients: 10 mg/mL Glycine, 8.5 mg/mL sodium chloride, 2.5 mg/mL sodium citrate</p>
ALTERNATIVES	<p>Non-blood product:</p> <p>Blood product:</p>
DOSAGE	<p>HAEGARDA is a lyophilized powder for reconstitution and injection:</p> <ul style="list-style-type: none"> • 2000 IU/vial • 3000 IU/vial • 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 administered subcutaneously in the abdominal area or other subcutaneous injection sites. • The maximum tolerated dose used in patients in clinical studies was 10,000IU, corresponding to a volume of 20 mL, twice weekly by subcutaneous injection.
ADMINISTRATION	<ul style="list-style-type: none"> • HAEGARDA is intended for self-administration by subcutaneous injection only. The patient or caregiver should be trained on how to administer HAEGARDA as needed
CLINICAL/ DIAGNOSTIC MONITORING	<ul style="list-style-type: none"> • N/A
CLINICAL INDICATIONS	<p>HAEGARDA (C1 Esterase Inhibitor Subcutaneous (Human)) is indicated for routine prevention of Hereditary Angioedema (HAE) attacks in adolescent and adult patients.</p> <p>Geriatrics: Clinical study has been performed in patients ≤72 years of age (<i>See section WARNINGS AND PRECAUTIONS, subsection <i>Special Populations</i></i>).</p> <p>Pediatrics:</p> <ul style="list-style-type: none"> • No clinical study has been performed in children <12 years of age (<i>See section WARNINGS AND PRECAUTIONS, subsection <i>Special Populations</i></i>).
SPECIAL CONSIDERATIONS	N/A
CONTRAINDICATIONS	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.

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STORAGE CONDITIONS	<p>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.</p> <p>Keep HAEGARDA in its original carton until ready to use. Do not freeze. Protect from light.</p> <ul style="list-style-type: none">• After reconstitution the physico-chemical stability has been demonstrated for 48 hours at room temperature (max. +30°C). From a microbiological point of view and as HAEGARDA contains no preservative, the reconstituted product should be used immediately. If it is not administered immediately, storage shall not exceed 8 hours at room temperature. The reconstituted product should only be stored in the vial.
REFERENCES	<p>HAEGARDA product monograph. August 13, 2019</p>

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