

Haegarda® (C1 esterase inhibitor [human]) – Expanded indication

- On September 28, 2020, <u>CSL Behring announced</u> the FDA approval of <u>Haegarda (C1 esterase inhibitor [human])</u>, for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in patients 6 years of age and older.
 - Haegarda was previously approved for this indication in adolescents and adults.
- The effectiveness of Haegarda for routine prophylaxis of HAE attacks was evaluated in a subgroup
 of nine patients 8 to < 17 years of age. Results of subgroup analysis by age were consistent with
 overall study results.
- The recommended dose of Haegarda for all patients is 60 IU per kg body weight by subcutaneous injection twice weekly (every 3 or 4 days).
 - Haegarda is intended for self (or caregiver)-administration after reconstitution. The patient or caregiver should be trained on how to administer Haegarda.



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