

Ruconest[®] (C1 esterase inhibitor [recombinant])



When requesting Ruconest[®] (C1 esterase inhibitor [recombinant]), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication¹

- Ruconest is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adult and adolescent patients.

Approved Off-label Compendial uses

- None

Coverage Guidelines

- Has a diagnosis of hereditary angioedema (HAE) confirmed by C4 and C1 inhibitor laboratory testing (i.e. low C4 levels, low C1 inhibitor antigenic protein levels, low C1 inhibitor functional levels)³
- Request is for the treatment of acute attacks of HAE^{1,2}
- Member does not have a history of HAE-related laryngeal attacks. Effectiveness has not been established for this indication¹
- Member is 13 years of age or older¹
- Member does not have a history of life-threatening immediate hypersensitivity reactions to C1 esterase inhibitor preparations including anaphylaxis (e.g., Cinryze, Berinert)¹
- Ruconest will not be used in combination with another agent for treating acute attacks of HAE (e.g., Berinert, Firazyr, Kalbitor)^{3,4}
- Member does not have a history of allergy to rabbits or rabbit-derived products¹

Additional Information for Prescribers¹

- Hypersensitivity reactions, including anaphylaxis, may occur. Ruconest should be immediately discontinued and appropriate treatment should be administered if symptoms occur.
- Serious arterial and venous thromboembolic (TE) events have been reported following Ruconest administration. Risk factors may include the presence of an indwelling venous catheter/access device, prior history of thrombosis, underlying atherosclerosis, use of oral contraceptives or certain androgens, morbid obesity, and immobility. Patients with known risk factors should be monitored for TE events during and after Ruconest administration.
- Ruconest is contraindicated in patients with a history of allergy to rabbits or rabbit-derived products.

References

1. Ruconest prescribing information. Raleigh NC; Salix Pharmaceuticals, Inc. February 2015. Available at <https://shared.salix.com/shared/pi/ruconest-pi.pdf>. Accessed January 07, 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed January 06, 2017. <http://www.micromedexsolutions.com/home/dispatch>
3. Craig, T, Pursun E, Bork, K, et al. WAO Guideline for the Management of Hereditary Angioedema. *World Allergy Organization Journal*. 2012; 5:182–199.
4. Zuraw, B, Banerji, A, Bernstein J, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency. *American Academy of Allergy, Asthma & Immunology*. 2013;1:458-67.