

ROUTINE PROPHYLACTIC DOSING WITH CINRYZE®

	Adult and adolescent patients (≥12 years)	Pediatric patients (6 to 11 years)
DOSE ¹	1,000 U intravenous For patients who have not responded adequately to 1,000 U of CINRYZE every 3 or 4 days, doses up to 2,500 U (not exceeding 100 U/kg) every 3 or 4 days may be considered based on individual patient response	500 U intravenous The dose may be adjusted according to individual response, up to 1,000 U every 3 to 4 days
DOSING REGIMEN ¹	Single dose can be administered every 3 or 4 days	
INFUSION RATE ¹	1 mL/min (10 minutes)	1 mL/min (5 minutes)

INDICATION

CINRYZE® (C1 esterase inhibitor [human]) is indicated for routine prophylaxis against angioedema attacks in adults, adolescents, and pediatric patients (6 years of age and older) with Hereditary Angioedema (HAE).

IMPORTANT SAFETY INFORMATION

Contraindications: CINRYZE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product.

Hypersensitivity Reactions: Severe hypersensitivity reactions may occur during or after administration of CINRYZE. Consider treatment methods carefully, because hypersensitivity reactions may have symptoms similar to HAE attacks. In case of hypersensitivity, discontinue CINRYZE infusion and institute appropriate treatment. Have epinephrine immediately available for treatment of an acute severe hypersensitivity reaction.

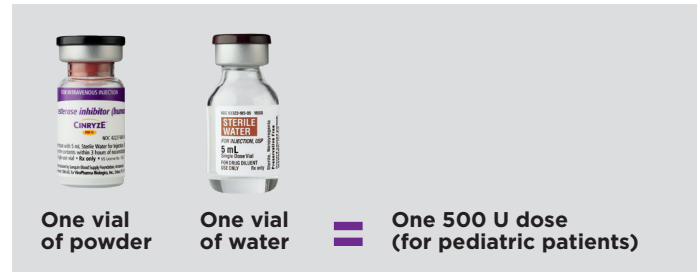
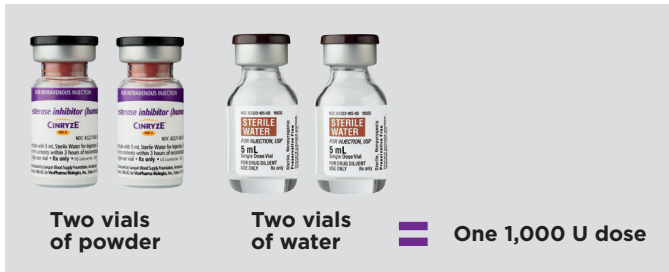
Thromboembolic Events: Serious arterial and venous thromboembolic (TE) events have been reported at the recommended dose of C1 Esterase Inhibitor (Human) products, including CINRYZE, following administration in patients with HAE. Risk factors may include presence of an indwelling venous catheter/access device, prior history of thrombosis, underlying atherosclerosis, use of oral contraceptives, certain androgens, morbid obesity, and immobility. Benefits of CINRYZE for routine prophylaxis of HAE attacks should be weighed against the risks of TE events in patients with underlying risk factors. Monitor patients with known risk factors for TE events during and after CINRYZE administration.

Transmissible Infectious Agents: Because CINRYZE is made from human blood, it may carry a risk of transmitting infectious agents, e.g. viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. ALL infections thought by a physician possibly to have been transmitted by CINRYZE should be reported to Shire Medical Information at 1-800-828-2088.

Please see additional Important Safety Information on the next page and click [here](#) for Full Prescribing Information.

CINRYZE®
C1 esterase inhibitor (human)

RECONSTITUTION OF CINRYZE®



For Intravenous Use Only

- ▷ CINRYZE® (C1 esterase inhibitor [human]) is available as a lyophilized preparation in single 500 U vials¹
- ▷ One vial of CINRYZE must be reconstituted for a 500 U dose¹
- ▷ Two vials of CINRYZE must be reconstituted for a 1,000 U dose¹
 - For higher doses up to 2,500 U (not exceeding 100 U/kg) for patients ≥12 years, additional vial(s) will need to be reconstituted
- ▷ Each vial of CINRYZE must be reconstituted with 5 mL of Sterile Water for Injection, USP (diluent) (not supplied)¹

CINRYZE® OFFERS ADMINISTRATION OPTIONS.

- ▷ CINRYZE can be self-administered or administered by a healthcare professional
- ▷ **Patients should only self-administer after being trained by a healthcare provider**

Please click [here](#) to read Full Prescribing Information for step-by-step reconstitution and administration instructions.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions: The only serious adverse reaction observed in clinical studies of CINRYZE was cerebrovascular accident. The most common adverse reactions (≥5%) observed were headache, nausea, rash, vomiting, and fever. Post marketing adverse reactions include local infusion site reactions and hypersensitivity. Post marketing thromboembolic events have been reported, including catheter-related and deep venous thromboses, transient ischemic attack, and stroke.

Before prescribing CINRYZE, click [here](#) for Full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Shire Medical Information at 1-800-828-2088 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference: 1. CINRYZE® (C1 esterase inhibitor [human]) Prescribing Information. Shire.



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