

PROLASTIN[®]-C LIQUID

Alpha₁-Proteinase Inhibitor (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROLASTIN[®]-C LIQUID safely and effectively. See full prescribing information for PROLASTIN-C LIQUID.

PROLASTIN[®]-C LIQUID (Alpha₁-Proteinase Inhibitor [Human])

Solution for Intravenous Injection

Initial U.S. Approval: 1987

INDICATIONS AND USAGE

PROLASTIN-C LIQUID is an Alpha₁-Proteinase Inhibitor (Human) (Alpha₁-PI) indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha₁-PI (alpha₁-antitrypsin deficiency).

Limitations of Use

- The effect of augmentation therapy with any Alpha₁-PI, including PROLASTIN-C LIQUID, on pulmonary exacerbations and on the progression of emphysema in Alpha₁-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials.
- Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with PROLASTIN-C LIQUID are not available.
- PROLASTIN-C LIQUID is not indicated as therapy for lung disease in patients in whom severe Alpha₁-PI deficiency has not been established.

DOSAGE AND ADMINISTRATION

For intravenous use only.

- Dose: 60 mg/kg body weight intravenously once per week.
- Dose ranging studies using efficacy endpoints have not been performed with any Alpha₁-PI product, including PROLASTIN-C LIQUID.
- Administration: 0.08 mL/kg/min as determined by patient response and comfort.

DOSAGE FORMS AND STRENGTHS

For injection: approximately 1,000 mg in a single-use vial containing 20 mL of solution for injection.

CONTRAINDICATIONS

- Immunoglobulin A (IgA) deficient patients with antibodies against IgA.
- History of anaphylaxis or other severe systemic reaction to Alpha₁-PI.

WARNINGS AND PRECAUTIONS

- Severe hypersensitivity and anaphylactic reactions may occur in IgA deficient patients with antibodies against IgA. Discontinue administration of the product and initiate appropriate emergency treatment if hypersensitivity reactions occur.
- Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

The most common adverse reactions during PROLASTIN-C LIQUID clinical trials in > 5% of subjects were diarrhea and fatigue, each of which occurred in 2 subjects (6%).

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

GRIFOLS

Grifols Therapeutics LLC

Research Triangle Park, NC 27709 USA

U.S. License No. 1871

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