

Prolastin[®]-C Liquid (alpha₁-proteinase inhibitor [human]) – New formulation approval

- On September 22, 2017, [Grifols announced the FDA approval](#) of [Prolastin-C Liquid \(alpha₁-proteinase inhibitor \[human\]\)](#) (alpha₁-PI), for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha₁-PI (alpha₁-antitrypsin deficiency).
 - Prolastin-C Liquid is a ready-to-infuse liquid formulation. Previously, Prolastin-C was only available as a lyophilized powder for reconstitution.
 - The effect of augmentation therapy with any alpha₁-PI, including Prolastin-C, 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 are not available.
 - Prolastin-C is not indicated as therapy for lung disease in patients in whom severe alpha₁-PI deficiency has not been established.
- Alpha₁-antitrypsin deficiency is an inherited disorder caused by a deficiency or absence of the alpha₁ protein in the plasma. The condition may lead to pulmonary emphysema without proper treatment and is the most common cause of liver disease in children. It affects an estimated 25 per 100,000 individuals.
 - Alpha₁-proteinase inhibitor [human] is also available as a lyophilized powder for reconstitution ([Aralast[®] NP](#), [Prolastin[®]-C](#), and [Zemaira[®]](#)) and as a ready-to-use solution ([Glassia[®]](#)).
- The efficacy of Prolastin-C in influencing the course of pulmonary emphysema or pulmonary exacerbations has not been demonstrated in adequately powered, randomized, controlled clinical trials.
- A double-blind, crossover pharmacokinetic study compared Prolastin-C Liquid to Prolastin-C.
 - The pharmacokinetic parameters of alpha₁-PI in plasma were comparable between Prolastin-C Liquid and Prolastin-C.
- Prolastin-C Liquid is contraindicated in IgA deficient patients with antibodies against IgA, due to risk of severe hypersensitivity; and in patients with a history of anaphylaxis or other severe systemic reaction to alpha₁-PI.
- Warnings and precautions with Prolastin-C Liquid include hypersensitivity reactions and transmissible infectious agents.
- The most common adverse reactions (> 5%) with Prolastin-C Liquid use were diarrhea and fatigue.
- The recommended dose for Prolastin-C Liquid is 60 mg/kg body weight administered intravenously once weekly.
 - A sterile 15 micron in-line filter should be used when administering this product.

- Grifols plans to launch Prolastin-C Liquid in 2018. Prolastin-C Liquid will be available as a 1 gram/20 mL solution for injection.



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