



Frequently Asked Questions

PROLASTIN-C LIQUID

1 What is different about PROLASTIN-C LIQUID?

PROLASTIN-C LIQUID is the same alpha₁-proteinase inhibitor found in the lyophilized powder version but now available in a convenient, ready-to-infuse liquid formulation, so preparation time is reduced because there is no need for reconstitution.^{1,2}

2 Have any new clinical data emerged to support PROLASTIN-C LIQUID?

Yes, a clinical study was conducted to evaluate the bioequivalence and safety of PROLASTIN-C LIQUID compared with the lyophilized powder version in patients with alpha₁-antitrypsin (AAT) deficiency, also known as alpha-1. Study results demonstrated that PROLASTIN-C LIQUID has a bioavailability and safety profile that is consistent with PROLASTIN-C lyophilized powder.¹

3 What was the design of this study?

A multicenter, randomized, double-blind crossover study was conducted to evaluate the bioequivalence, safety, and immunogenicity of PROLASTIN-C LIQUID compared with PROLASTIN-C lyophilized powder. Thirty-two patients with alpha-1 started on either PROLASTIN-C LIQUID or PROLASTIN-C lyophilized powder for 8 weekly IV infusions before switching to the opposite therapy for another 8 weekly IV infusions.¹

4 How do the safety and efficacy of PROLASTIN-C LIQUID compare to PROLASTIN-C lyophilized powder?

Because it's the same active medication, PROLASTIN-C LIQUID demonstrated the ability to effectively raise AAT levels to match levels measured with PROLASTIN-C lyophilized powder. PROLASTIN-C LIQUID has also been shown to have a safety profile that is consistent with the lyophilized formulation.^{1,2}

- 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%)

5 How is PROLASTIN-C LIQUID stored, and what stability information do you have?

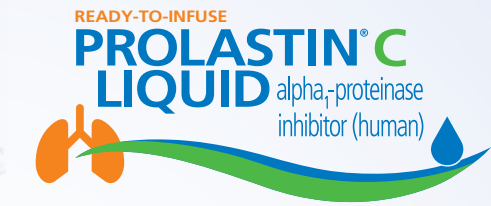
PROLASTIN-C LIQUID is stable for up to 2 years when refrigerated, and for 1 month at room temperature.¹

Indication

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).

Please see full Important Safety Information on back cover, and refer to accompanying full Prescribing Information for PROLASTIN-C LIQUID.

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Frequently Asked Questions

PROLASTIN-C LIQUID (cont'd)

6 How is PROLASTIN-C LIQUID different from other alpha-1 therapies?

PROLASTIN-C LIQUID allows for a low infusion volume of 20 mL/g. It has a fast infusion time of approximately 15 minutes—the same as PROLASTIN-C lyophilized powder, but without the added reconstitution time.^{1,3*}

7 How do you use PROLASTIN-C LIQUID? Is it easy to use?

PROLASTIN-C LIQUID is available in single-use, ready-to-infuse vials. Infusion is the same as with PROLASTIN-C lyophilized powder, but there is no reconstitution required, saving preparation time.^{1,3}

8 Are patients able to self-infuse?

The decision to self-infuse should be made between a patient and his/her provider. As a part of the infusion support services available through the PROLASTIN DIRECT program, self-infusion training is available when it is determined that it is the best fit for the patient's needs.

9 When and where is PROLASTIN-C LIQUID available?

PROLASTIN-C LIQUID is available now. As with PROLASTIN-C lyophilized powder, PROLASTIN-C LIQUID is available ONLY through PROLASTIN DIRECT and its speciality pharmacy supplier, Dohmen Life Science Services.⁴

PROLASTIN DIRECT®

1 Will I/my office staff still have access to PROLASTIN DIRECT and a dedicated specialty team?

Absolutely. You and your staff will still enjoy all the benefits of PROLASTIN DIRECT, including a dedicated alpha-1 coordinator who⁴:

- Is specifically assigned to support you and your patients
- Manages the PROLASTIN DIRECT streamlined enrollment process
- Relieves the administrative burden of starting your patients on therapy
- Connects your patients to the peer-to-peer support provided through the AlphaNet® Alpha-1 Disease Management and Prevention Program (ADMAPP)

2 Will I/my patients still receive the same service and support from PROLASTIN DIRECT?

Yes. When you enroll in PROLASTIN DIRECT, you, your office staff, and your patients will gain immediate access to the personalized service and comprehensive benefits beyond therapy offered by PROLASTIN DIRECT, including:

- Access to PROLASTIN-C LIQUID—a ready-to-infuse liquid formulation^{3,5}
- One dedicated coordinator specifically designed to support you and your patients⁴
- Insurance and reimbursement specialists focused solely on alpha-1, with >90% success in acquiring patient coverage⁵

*When given at the recommended rate of 0.08 mL/kg/min.

Frequently Asked Questions

PROLASTIN DIRECT (cont'd)

- 24/7 on-call support with specially trained registered nurses and pharmacists dedicated exclusively to alpha-1 care⁴
- Automatic enrollment in a disease management and prevention program (AlphaNet) clinically demonstrated to improve health outcomes⁴

Call 1-800-305-7881 to speak with a dedicated Patient Service Coordinator.

3 Are the coverage and copay the same?

There is no price difference between PROLASTIN-C LIQUID and PROLASTIN-C lyophilized powder, and coverage is expected to remain consistent as well.

Additionally, a dedicated PROLASTIN DIRECT alpha-1 coordinator will still help your patients to⁴:

- Navigate the insurance and reimbursement process
- Manage the preauthorization and verification process for treatment and benefits
- Assist with any complexities that may arise

4 What kind of paperwork is involved?

Starting patients on PROLASTIN-C LIQUID is the same process as starting them on PROLASTIN-C lyophilized powder. Simply fill out a PROLASTIN DIRECT enrollment form that includes the prescription for PROLASTIN-C LIQUID and fax it to PROLASTIN DIRECT, or call 1-800-305-7881 to speak with a dedicated Patient Service Coordinator. In addition, the insurance and reimbursement specialists of the PROLASTIN DIRECT program are focused solely on alpha-1 and will help you through each step of the process.

Conversion from lyophilized powder to liquid

1 With the launch of the liquid formulation, will the lyophilized powder formulation still be available for my patients?

Yes. PROLASTIN-C lyophilized powder will continue to be available for your patients. However, the goal is to seamlessly transition all patients to PROLASTIN-C LIQUID over time.

2 Will there be a sufficient supply of PROLASTIN-C LIQUID at launch?

Yes. PROLASTIN-C LIQUID offers all the benefits and advantages you would expect from the #1-prescribed alpha-1 therapy, care, and support, including a reliable product supply.

Important Safety Information

PROLASTIN-C LIQUID is contraindicated in immunoglobulin A (IgA)-deficient patients with antibodies against IgA or patients with a history of anaphylaxis or other severe systemic reaction to alpha₁-PI products.

Please see full Important Safety Information on back cover, and refer to accompanying full Prescribing Information for PROLASTIN-C LIQUID.

Frequently Asked Questions

Conversion from lyophilized powder to liquid (cont'd)

3 What is the plan for conversion to the liquid formulation?

Because PROLASTIN-C LIQUID is appropriate for all your alpha-1 patients, our goal is to transition all existing patients to PROLASTIN-C LIQUID over time.

4 How is the conversion going to affect me, my office staff, and my patients?

You and your patients can feel confident that the PROLASTIN DIRECT® program will make transitioning to new PROLASTIN-C Liquid a smooth and easy process. A PROLASTIN DIRECT coordinator will contact you to obtain an updated prescription when your patient is ready to make the switch—this will often occur when their current prescription has no refills remaining. For more information, contact your sales specialist, or call 1-800-305-7881 to speak with a dedicated Patient Service Coordinator who is there to help you each step of the way.

Important Safety Information

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

PROLASTIN-C LIQUID is contraindicated in immunoglobulin A (IgA)-deficient patients with antibodies against IgA or patients with a history of anaphylaxis or other severe systemic reaction to alpha₁-PI products.

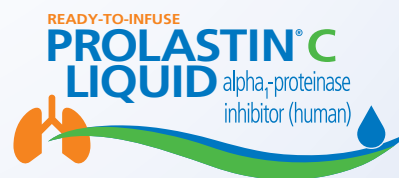
Hypersensitivity reactions, including anaphylaxis, may occur. Monitor vital signs and observe the patient carefully throughout the infusion. If hypersensitivity symptoms occur, promptly stop PROLASTIN-C LIQUID infusion and begin appropriate therapy.

Because PROLASTIN-C LIQUID is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens.

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%).

Please see accompanying full Prescribing Information for PROLASTIN-C LIQUID.

References: 1. Barker A, Campos M, Brantly M, et al. Bioequivalence of a liquid formulation of alpha₁-proteinase inhibitor compared with Prolastin®-C (lyophilized alpha₁-PI) in alpha₁-antitrypsin deficiency. *COPD*. 2017;14(6):590-596. 2. Data on file, Executive Summary, Grifols. 3. PROLASTIN®-C LIQUID (alpha₁-proteinase inhibitor [human]) Prescribing Information, Grifols. 4. Data on file, PROLASTIN DIRECT, Alpha-1 support, Grifols. 5. Data on file, PROLASTIN DIRECT program, Grifols.



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