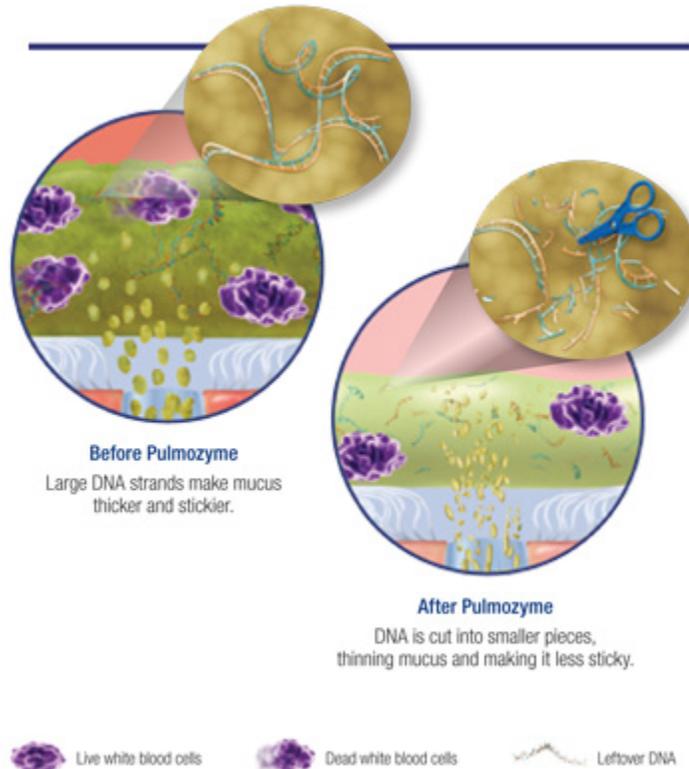


How Pulmozyme (dornase alfa) addresses abnormal mucus

In laboratory tests, Pulmozyme has been shown to thin and loosen the mucus. Pulmozyme is the only treatment for CF that functions like “scissors” within the mucus, cutting up the DNA that makes mucus thick and sticky. Thick, sticky mucus could build up and lead to blockages in the airways.



Why Pulmozyme is an important part of a preventive treatment plan

Along with other standard therapies, Pulmozyme may help delay CF progression by improving lung function and reducing the risk for respiratory tract infections.

In studies of patients with mild to moderate disease (defined as FVC of at least 40% of predicted), Pulmozyme helped patients improve their lung function as measured by FEV₁ by approximately 6%. In comparison, the lung function of patients who did not take Pulmozyme stayed roughly the same.

For patients with CF, repeated respiratory tract infections can lead to more rapid decline in lung function. Studies have also shown that patients who used Pulmozyme daily reduced the relative risk of respiratory tract infections by 27% as compared to patients who did not take Pulmozyme.

Since it was introduced in 1994, Pulmozyme has been an important part of CF treatment for many patients.

If you care for a child under the age of 5...

There is limited experience with the administration of Pulmozyme in patients under 5, so its use should be considered only for those patients in whom there is a potential for benefit in lung function or in risk of respiratory tract infections.

To learn more about the safety of Pulmozyme in pediatric patients, one study assessed its use in two age groups: younger patients (3 months to less than 5 years of age) and older patients (5 years to less than 10 years of age).

In this study, side effects were generally similar in both age groups. There were more reports of cough, moderate to severe cough, runny nose, and rash in the younger group of patients. The kind of side effects reported was similar to that of Pulmozyme when used in larger trials that studied older patients.

Important Safety Information

Pulmozyme should not be used in patients who are allergic to any of its ingredients. Pulmozyme should be used in conjunction with standard therapies for CF. When starting Pulmozyme therapy, patients may experience change in or loss of voice, discomfort in the throat, chest pain, red watery eyes, rash, dizziness, fever, or runny nose. These side effects are usually mild and short-lived.

Pediatric Use

There is a limited amount of information available concerning the usage of Pulmozyme in patients who are younger than 5 years. The decision to use Pulmozyme in these patients is made after considering the potential for a benefit in lung function or in decreasing the risk of RTEs.

Important Safety Considerations

The safety of Pulmozyme given by daily inhalation for 2 weeks has been studied using 98 CF patients with 65 of them aged 3 months to <5 years (younger group) and 33 aged 5 years to ≤10 years (older group). The PARI BABY™ reusable nebulizer (which uses a face mask instead of a mouthpiece) was used in patients who were unable to show that they could breathe in or out using their mouth throughout the entire treatment period. There were more reports of cough, moderate to severe cough, runny nose, and rash in the younger group of patients. Other reported events tended to be of mild to moderate severity. The kind of side effects reported was similar to that of Pulmozyme when used in the larger trials that studied older patients.

For more information www.pulmozyme.com