



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Cayston®

Common Name: Aztreonam

PDL Category: Antibiotics-Misc.

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Tobi®	Preferred

Summary

Indications and Usage: Indicated to improve respiratory symptoms in cystic fibrosis (CF) patients 7 years of age or older with *Pseudomonas aeruginosa* (*P. aeruginosa*).¹

Mechanism of Action: Antibacterial drug with potent *in vitro* activity against gram-negative aerobic pathogens, including *Pseudomonas aeruginosa*.¹

Dosage Forms: Powder for solution, lyophilized; inhalation: 75mg¹

Recommended Dosage: 75mg three times daily administered with the Altera® Nebulizer System for 28 days.¹

Common Adverse Drug Reactions: Cough, wheezing, nasal congestion, pharyngolaryngeal pain, pyrexia, chest discomfort, abdominal pain, and vomiting.¹

Contraindications: Do not administer to patients with a known allergy to aztreonam.¹

Manufacturer: Gilead Sciences, Inc.

Analysis: Cayston® is a new inhaled antibiotic approved to improve respiratory symptoms in CF patients with *P. aeruginosa*. Cayston® is to be administered by inhalation using the Altera Nebulizer System, an inhalation delivery device specifically for use with Cayston®. Patients should use a bronchodilator prior to Cayston® administration. Caution should be used when administering Cayston® to patients with a history of beta-lactam allergy. In the trials used to gain FDA approval, Cayston™ was compared to placebo. The primary efficacy endpoint for the trial was improvement in respiratory symptoms on the last day of treatment with Cayston® or placebo, as reported by a patient questionnaire. Statistically significant improvements in respiratory symptoms were seen in Cayston® treated patients as compared to placebo. The improvement was substantially smaller in adult patients versus pediatric patients. The improvement in FEV₁(L) from baseline was also statistically significant at 10% in the Cayston® treated group compared to the placebo treated group. Safety and efficacy have not been established in patients below the age of 7, patients with FEV₁ less than 25% or greater than 75% predicted, and in patients colonized with *Burkholderia cepacia*. It is recommended that Cayston® be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation: Preferred Drug Recommended Drug
 Non-Preferred Drug Non-Recommended Drug

1. Cayston® [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2010.

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