

FDA-Approved Patient Labeling

Patient Information

CAYSTON® (kay-stun) (aztreonam for inhalation solution)

Read this Patient Information before you start taking CAYSTON and each time you get a refill. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is CAYSTON?

CAYSTON is a prescription inhaled antibiotic. CAYSTON is used to improve breathing symptoms in people with cystic fibrosis (CF) who have *Pseudomonas aeruginosa* (*P. aeruginosa*) in their lungs.

CAYSTON is only for infections caused by bacteria. It is not for infections caused by viruses, such as the common cold.

CAYSTON is used only with the Altera® Nebulizer System.

It is not known if CAYSTON is safe and effective in children under the age of 7.

Who should not take CAYSTON?

Do not take CAYSTON if you are allergic to aztreonam (AZACTAM®).

What should I tell my doctor before taking CAYSTON?

Before taking CAYSTON, tell your doctor if you:

- are allergic to any antibiotics.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast feed.

Talk to your doctor about the best way to

breast feed your baby if you take CAYSTON.

Tell your doctor about all the medicine you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take CAYSTON?

- Take CAYSTON exactly as prescribed by your doctor.
- The dose of CAYSTON for both adults and children 7 years of age and older is one vial of CAYSTON, mixed with one ampule of saline (diluent) 3 times a day.
- Doses of CAYSTON should be taken at least 4 hours apart (for example: morning, after school, and before bed).
- CAYSTON should be taken for 28 days.
- CAYSTON is taken as a breathing treatment (inhalation) with the Altera Nebulizer System. Do not use any other nebulizer for your CAYSTON treatment.
- You should use an inhaled bronchodilator (a type of medicine used to relax and open your airways) before taking a dose of CAYSTON. If you do not have an inhaled bronchodilator, ask your doctor to prescribe one for you.
- If you are taking several medicines or treatments to treat your cystic fibrosis, you should take your medicines or other treatments in this order:

- 1) bronchodilator
 - 2) mucolytics (medicines to help clear mucus from your lungs)
 - 3) CAYSTON
- You should take CAYSTON as prescribed, in courses of 28 days on CAYSTON, followed by at least 28 days off CAYSTON, as directed by your doctor.
 - Do not mix CAYSTON with any other medicines in your Altera Nebulizer System.
 - Do not mix CAYSTON with the saline until right before you are ready to use it. Do not mix more than one dose of CAYSTON at a time.
 - Each treatment should take about 2 to 3 minutes.
 - If you miss a dose of CAYSTON, you can still take all 3 daily doses as long as they are at least 4 hours apart.
 - It is important for you to finish taking the full 28-day course of CAYSTON even if you are feeling better. If you skip doses or do not finish the full 28-day course of CAYSTON, your infection may not be fully treated and CAYSTON may not work as well as a treatment for infections in the future.
 - See the end of this Patient Information leaflet for the Patient Instructions for Use on how to take CAYSTON the right way.
- Rash or swelling of your face
 - Throat tightness
 - **Trouble breathing right after treatment with CAYSTON (bronchospasm).** To decrease the chance of this happening, be sure to use your inhaled bronchodilator medicine before each treatment with CAYSTON. See “How should I take CAYSTON?”

Common side effects of CAYSTON

include:

- Cough
- Nasal congestion
- Wheezing
- Sore throat
- Fever. Fever may be more common in children than in adults.
- Chest discomfort
- Stomach area (abdominal) pain
- Vomiting

Tell your doctor if you have any new or worsening symptoms while taking CAYSTON. Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects of CAYSTON. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CAYSTON?

- Each CAYSTON kit contains enough vials of CAYSTON and ampules of saline for 28 days of treatment. There are 4 extra saline ampules in case some saline spills.

What are the possible side effects of CAYSTON?

CAYSTON can cause serious side effects, including:

- **Severe allergic reactions. Stop your treatment with CAYSTON and call your doctor right away if you have any symptoms of an allergic reaction, including:**

- Always keep your CAYSTON and saline together.
- Store CAYSTON and saline in the refrigerator at 36 °F to 46 °F (2 °C to 8 °C) until needed.
- When you remove CAYSTON and saline from the refrigerator, they may be stored at room temperature (less than 77 °F) for up to 28 days. Do not use any CAYSTON that has been stored at room temperature for more than 28 days.
- Keep CAYSTON away from light.
- Do not use CAYSTON after the expiration date on the vial. Do not use the saline after the expiration date on the ampule.

Keep CAYSTON and all medicines out of the reach of children.

General information about CAYSTON

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CAYSTON for a condition for which it was not prescribed. Do not give CAYSTON to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about CAYSTON. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about CAYSTON that is written for health professionals.

For more information, call 1-877-7CAYSTON (1-877-722-9786).

What are the ingredients in CAYSTON?

Active ingredient: aztreonam

Inactive ingredient: sodium chloride (diluent)

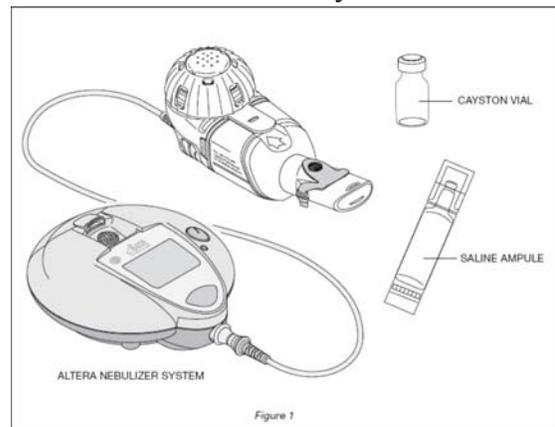
Patient Instructions for Use

CAYSTON® (aztreonam for inhalation solution)

Be sure that you read, understand and follow the Patient Instructions for Use below for the right way to take CAYSTON. If you have any questions, ask your doctor or pharmacist.

You will need the following supplies (Figure 1):

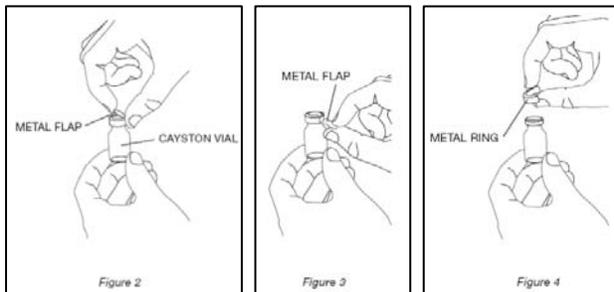
- 1 amber colored CAYSTON vial
- 1 ampule of saline (diluent)
- Altera Nebulizer System



Check to make sure that your Altera Nebulizer System works properly before starting your treatment with CAYSTON. See the manufacturer's instructions for use that comes with your Altera Nebulizer System. This should have complete information about how to put together (assemble), prepare, use, and care for your Altera Nebulizer System.

Step 1 Preparing your CAYSTON for inhalation

1. Mix (reconstitute) CAYSTON with the saline only when ready to take a dose. Take one amber vial of CAYSTON and one ampule of saline from the carton. Separate the saline ampules by gently pulling apart.
2. Look at the ampule of saline. If it looks cloudy do not use it. Throw away this ampule and get another ampule of saline.
3. Gently tap the vial so that the powder settles to the bottom of the vial. This helps you get the proper dose of medicine. Open the amber drug vial by lifting up the metal flap on the top (Figure 2) and pulling down (Figure 3) to carefully remove the entire metal ring from the vial (Figure 4). Safely dispose of the ring in household garbage. Carefully remove the rubber stopper.



4. Open the ampule of saline by twisting off the tip. Squeeze out the contents completely into the vial (Figure 5). Next, close the vial with the rubber stopper and gently swirl the vial until the powder has completely dissolved and the liquid is clear.



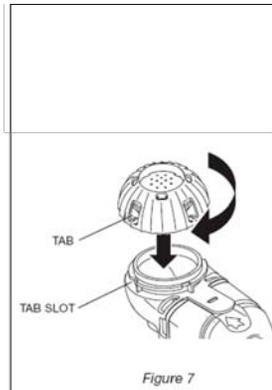
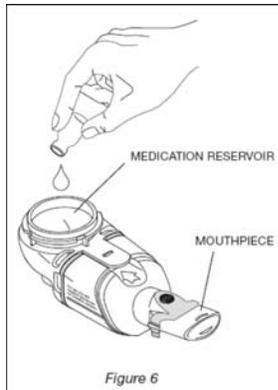
Figure 5

5. After mixing CAYSTON with the saline, check to make sure the diluted medicine is clear. If it is cloudy or has particles in it, do not use this medicine. Throw away this dose of medicine and start over again with a new vial of CAYSTON and a new ampule of saline.
6. Use CAYSTON right away after you mix with the saline.

Step 2 Taking your CAYSTON treatment

See the manufacturer's instructions for use that comes with your Altera Nebulizer System for complete instructions on taking a treatment, and how to clean and disinfect your Altera Nebulizer Handset.

7. Make sure the handset is on a flat, stable surface.
8. Remove the rubber stopper from the vial, then pour all of the mixed CAYSTON and saline into the Medication Reservoir of the handset (Figure 6). Be sure to completely empty the vial, gently tapping the vial against the side of the Medication Reservoir if necessary. Close the Medication Reservoir (Figure 7).



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9. Begin your treatment by sitting in a relaxed, upright position. Hold the handset level, and place the Mouthpiece in your mouth. Close your lips around the Mouthpiece (Figure 8).



10. Breathe in and out normally (inhale and exhale) through the Mouthpiece. **Avoid breathing through your nose.** Continue to inhale and exhale comfortably until the treatment is finished.
11. The empty vial, stopper and saline ampule should be disposed of in household garbage upon completion of dosing.

Manufactured by: Gilead Sciences, Inc., Foster City, CA 94404

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