

PATIENT INFORMATION
CAYSTON® (kay-stun)
(aztreonam for inhalation solution)
for oral inhalation use

What is CAYSTON?

CAYSTON is a prescription medicine that is used to improve breathing symptoms in people with cystic fibrosis (CF) who have a lung infection caused by a bacterium called *Pseudomonas aeruginosa*. CAYSTON contains an antibacterial medicine called aztreonam.

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

It is not known if CAYSTON is safe and effective:

- in children under 7 years of age
- in people who have an FEV₁ less than 25% or greater than 75% predicted
- in people who are colonized with a bacterium called *Burkholderia cepacia*

Do not take CAYSTON if you are allergic to aztreonam, or any of the ingredients in CAYSTON.

See the end of this Patient Information for a complete list of ingredients in CAYSTON.

Before you take CAYSTON, tell your healthcare provider about all of your medical conditions, including if you:

- are allergic to any antibiotics.
- are pregnant or plan to become pregnant. It is not known if CAYSTON can harm your unborn baby.
- are breastfeeding or plan to breastfeed. CAYSTON can pass into your breastmilk. Talk with your healthcare provider about the best way to feed your baby while you are taking CAYSTON.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may affect how CAYSTON works.

How should I take CAYSTON?

- **See the step-by-step Instructions for Use** about the right way to take your CAYSTON.
- Take CAYSTON exactly as your healthcare provider tells you. **Do not** change your dose or stop taking CAYSTON unless your healthcare provider tells you to.
- The dose for both adults and children 7 years of age and older is:
 - 1 single-use vial of CAYSTON, mixed with 1 ampule of saline (diluent) inhaled 3 times a day using a hand-held Altera Nebulizer System.
- Each dose 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.
- **Do not** mix or dilute 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 1 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.
- 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 healthcare provider to prescribe one for you.
 - Take short-acting bronchodilators between 15 minutes and 4 hours before you take your dose of CAYSTON
 - Take long-acting bronchodilators between 30 minutes and 12 hours before you take your dose of CAYSTON
- 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

- After taking CAYSTON for 28 days, you should stop taking it and wait 28 days. Complete the full 28-day course of CAYSTON even if you are feeling better. It is important that you keep to the 28-day on, 28 day off cycle.
- 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.

What are the possible side effects of CAYSTON?

CAYSTON may cause serious side effects, including:

- Severe allergic reactions. Stop your treatment with CAYSTON and call your healthcare provider right away if you have any symptoms of an allergic reaction, including:
 - Rash or swelling of your face
 - Throat tightness
- Trouble breathing right after treatment with CAYSTON (bronchospasm). Tell your healthcare provider right away if you get any of these symptoms of bronchospasm with using CAYSTON:
 - shortness of breath with wheezing
 - coughing and chest tightnessTo 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?”

The most 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

Other possible side effects of CAYSTON include swelling or pain in joints.

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

These are not all the possible side effects of CAYSTON.

Call your healthcare provider 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 single-use vials of CAYSTON and ampules of saline for 28 days of treatment. There are 4 extra saline ampules in case some saline spills.
- Always keep your CAYSTON and saline together.
- Store CAYSTON and saline in the refrigerator between 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 (up to 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 the safe and effective use of 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. You can ask your pharmacist or healthcare provider for information about CAYSTON that is written for health professionals.

What are the ingredients in CAYSTON?

Active ingredient: aztreonam

Inactive ingredient: lysine, sodium chloride (diluent)

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

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

This Patient Information has been approved by the U.S. Food and Drug Administration

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PATIENT INSTRUCTIONS FOR USE

CAYSTON® (aztreonam for inhalation solution) for oral inhalation use

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 healthcare provider or pharmacist.

You will need the following supplies (Figure 1):

- 1 amber colored CAYSTON vial covered by a metal seal with a blue cap
- 1 ampule of saline (diluent)
- Altera Nebulizer System

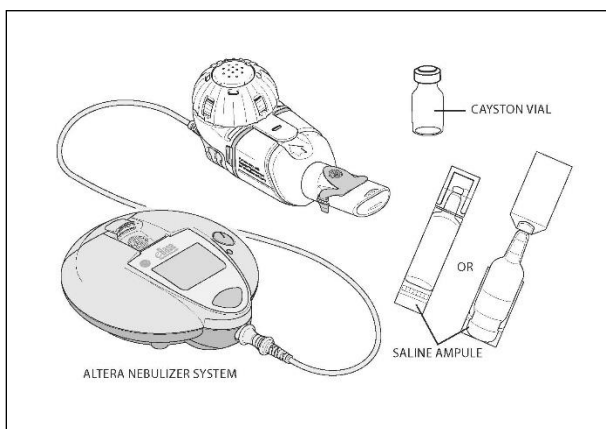


Figure 1

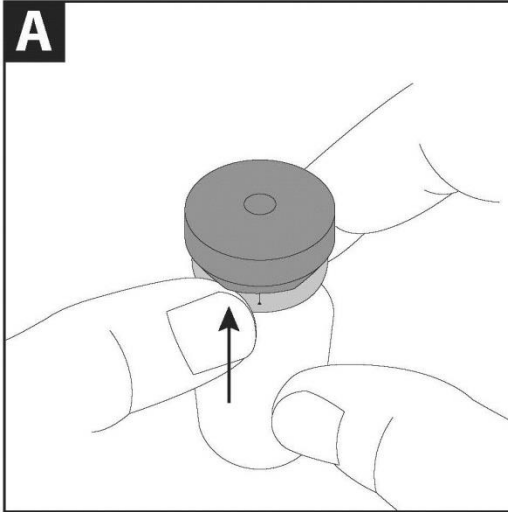
Check to make sure that your Altera Nebulizer System works properly before starting your treatment with CAYSTON. See the manufacturer's instructions for use that comes with your Altera Nebulizer System. This should have complete information about how to put together (assemble), prepare, use, and care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

Preparing your CAYSTON for Inhalation

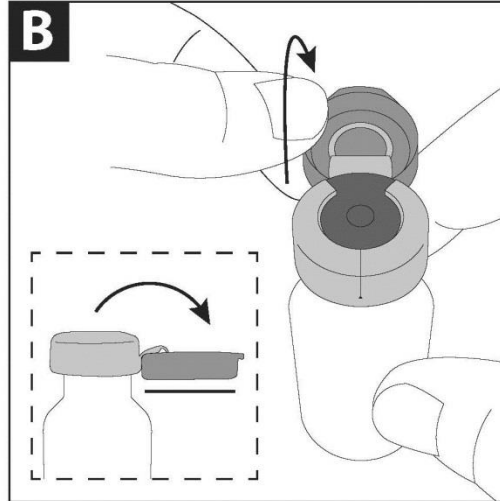
Step 1. Mix (reconstitute) CAYSTON with the saline only when ready to take a dose. Take 1 amber vial of CAYSTON and 1 ampule of saline from the carton. Separate the saline ampules by gently pulling apart.

Step 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.

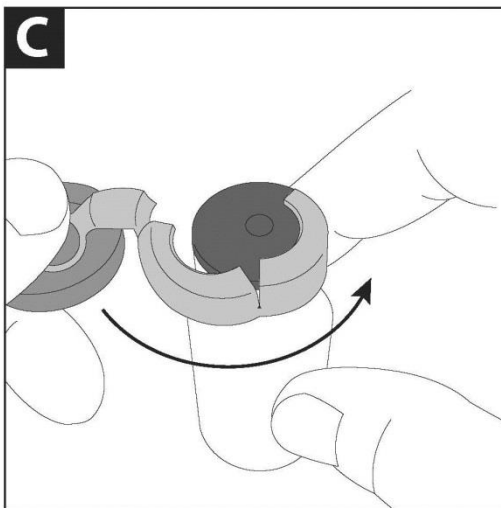
Step 3. Gently tap the vial so that the powder settles to the bottom of the vial. This helps you get the proper dose of medicine. Follow **Step A to Step D** in Figure 2 below to open the vial:



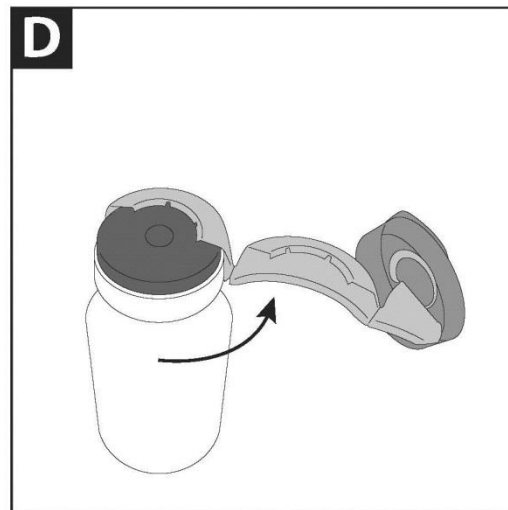
Step A: With the blue cap tab facing toward you, place the vial on a flat surface. Using **one hand** to hold the vial steady, use the **other hand** to slowly flip up the blue cap.



Step B: Pull the blue cap down to a flat (horizontal) position (where the bottom of the blue cap faces up), to prepare the metal seal for removal. **Do not** completely tear through the metal seal.



Step C: While continuing to hold the vial steady with **one hand**, use the **other hand** to slowly pull the blue cap in a **counterclockwise** direction. **Do not** twist the blue cap.



Step D: When the metal seal opens, continue to slowly pull the blue cap in a **counterclockwise** direction until the metal seal is completely removed.

Figure 2

Step 4. Safely throw away (dispose of) the metal seal in household garbage. Carefully remove (but **do not** yet discard) the rubber stopper.

Step 5. Open the ampule of saline by twisting off the tip. Squeeze out the contents completely into the vial (**Figure 3**). Next, close the vial with the rubber stopper and gently swirl the vial until the powder has completely dissolved and the liquid is clear.

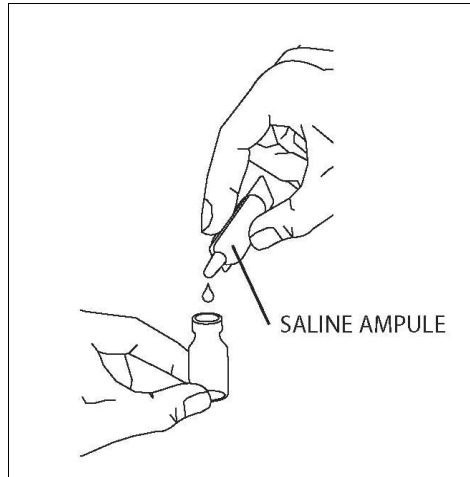


Figure 3

Step 6. 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.

Step 7. Use CAYSTON right away after you mix with the saline.

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.

Step 8. Make sure the handset is on a flat, stable surface.

Step 9. Remove the rubber stopper from the vial, then pour all of the mixed CAYSTON and saline into the Medication Reservoir of the handset (Figure 4). 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 5).

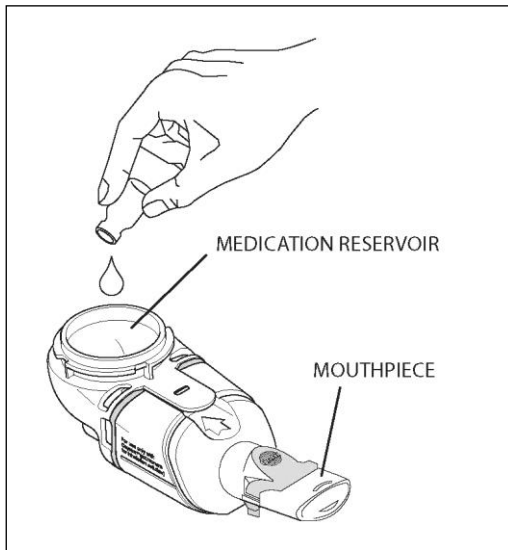


Figure 4

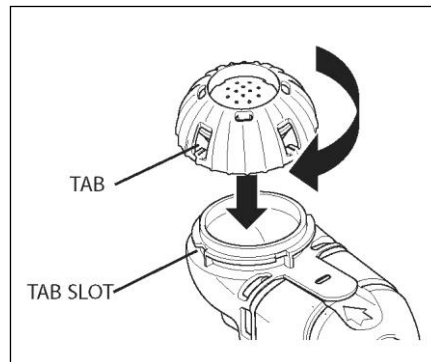


Figure 5

Step 10. 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 6).

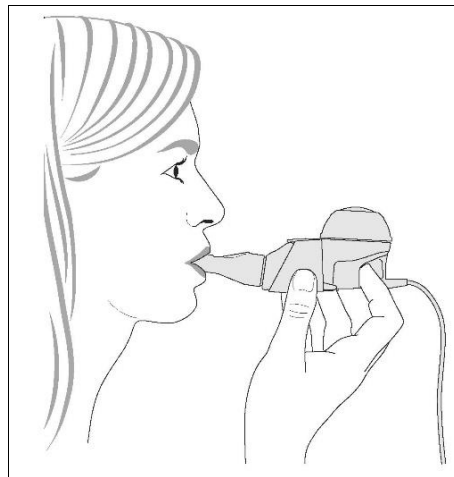


Figure 6

Step 11. 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.

Step 12. The empty vial, stopper and saline ampule should be disposed of in household garbage upon completion of dosing.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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

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