

## 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 the bacteria *Pseudomonas aeruginosa*. It is not for infections caused by viruses, such as the common cold. Take Cayston as prescribed by your doctor to treat your current infection. Using Cayston for infections other than as prescribed by your doctor may increase the development of drug-resistant bacteria and could stop your Cayston from working.

Cayston can only be taken with the Altera Nebulizer System. Do not use any other nebulizer for your Cayston treatment.

It is not known if Cayston is safe and effective in children under the age of 7 or in patients with FEV<sub>1</sub> <25% or >75% predicted.

## Who should not take Cayston?

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

## What you should tell your doctor before taking Cayston

Before taking Cayston, tell your doctor if you are:

- Allergic to any antibiotics
- Pregnant or plan to become pregnant
- 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.

Please see the Important Safety Information in column 3 and the attached Cayston Full Prescribing Information, and read the complete FDA-Approved Patient Labeling, including the Instructions for Use. See the manufacturer's instructions for use that come with your Altera Nebulizer System.

## How should I take Cayston?

- Take Cayston exactly as prescribed by your doctor.
- A dose of Cayston for both adults and children 7 years of age and older is 1 vial of Cayston, mixed with 1 ampule of saline (diluent) 3 times a day.
- Doses of Cayston should be taken 3 times a day with at least 4 hours between each dose.
- One course of treatment with Cayston means taking Cayston 3 times a day for 28 days, followed by at least 28 days off Cayston as directed by your doctor.

Before taking a dose of Cayston, you should use an inhaled bronchodilator (a type of medicine used to relax and open your airways).

If taking several medicines or treatments for your CF, take them in this order:

- Bronchodilator
- Mucolytics (medicines to help clear mucus from your lungs)
- Cayston

Do not mix Cayston with any other medicines in your Altera Nebulizer System.

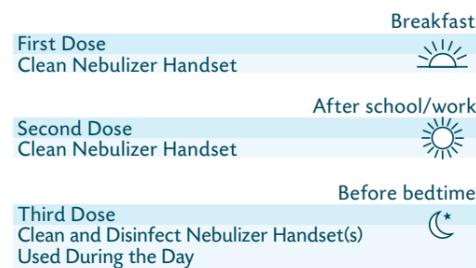
Do not mix Cayston with the saline until right before you are ready to use it.

Do not mix more than 1 dose of Cayston at a time.

See detailed cleaning and disinfecting instructions on other side.

### Sample Dosing Schedule

Doses of Cayston should be taken 3 times a day, at least 4 hours apart.



## What to do if you miss a dose

- 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 that you finish taking the full 28-day course, even if you are feeling better.
- If you skip doses or do not finish the full 28-day course, your infection may not be fully treated. As a result, Cayston may not work as well as a treatment for infections in the future.

## 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:
  - Rash or swelling of your face
  - Throat tightness

If you have a history of allergy to antibiotics such as penicillins, cephalosporins, and/or carbapenems, you may also be allergic to Cayston. It is important to tell your healthcare provider about any medication allergies you may have.

- 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. Stop treatment if chest tightness develops during nebulizer use.
- Decreases in FEV<sub>1</sub> after 28-day course of treatment. Improvements that you experience in your lung function during your 28-day course of treatment may not be continued when you stop treatment.

Common side effects of Cayston include:

- Cough
- Nasal congestion
- Wheezing
- Sore throat
- Fever (may be more common in children than 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 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 the 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.
- 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.

Information continues in next column.

- 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.

## How to take Cayston with the Altera Nebulizer System:

fast nebulization in about 2 to 3 minutes, 3 times a day

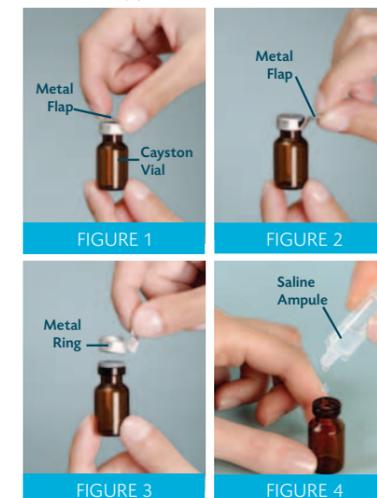
Check to make sure that your Altera Nebulizer System works properly before starting your treatment with Cayston. See the manufacturer's instructions for use that come with your Altera Nebulizer System. This should have complete information about how to put together (assemble), prepare, use, and care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

## Preparing your Cayston for inhalation

You will need the following supplies:

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

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.
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 1) and pulling down (Figure 2) to carefully remove the entire metal ring from the vial (Figure 3). Safely dispose of the ring in household garbage. Carefully remove the rubber stopper.

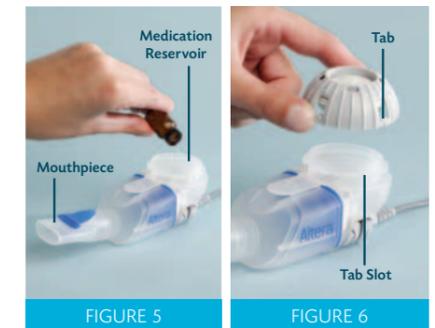


Information continues in next column.

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

## Taking your Cayston treatment

1. Make sure the Handset is on a flat, stable surface.
2. Remove the rubber stopper from the vial, then pour all of the mixed Cayston and saline into the Medication Reservoir of the Handset (Figure 5). 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 6).



3. 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 7).



4. 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.
5. The empty vial, stopper, and saline ampule should be disposed of in household garbage upon completion of dosing.

Please see the Important Safety Information and the attached Causton Full Prescribing Information, and read the complete FDA-Approved Patient Labeling, including the Instructions for Use. See the manufacturer's instructions for use that come with your Altera Nebulizer System.

Libby, age 27 and Sam, age 30, are sisters living with CF who take Causton as prescribed by their doctor.



A step-by-step dosing, administration, and cleaning guide for Causton® and the Altera® Nebulizer System

## Causton must be used with the Altera Nebulizer System

The Altera Nebulizer System has been designed specifically for use only with Causton. It is a lightweight, portable, and quiet way to deliver Causton. Causton is the only medication that has demonstrated efficacy and safety with the Altera Nebulizer System. The nebulization time is fast. Each dose should take about 2 to 3 minutes. It is important to remember:

- Do not use any other nebulizer for your Causton treatment.
- Do not use any medication other than Causton in the Altera Nebulizer System.
- Use of drugs other than Causton in the Altera Nebulizer System could result in potential incorrect dosage or overdoses of medication.
- Use of other drugs could clog the Altera Aerosol Head, which may cause nebulization of your Causton treatment to be ineffective and shorten the useful life of the device.



## How to clean and disinfect your Altera Nebulizer Handset

To reduce risk of infection, illness, and/or injury from contamination and/or improper use, clean the Altera Nebulizer Handset as soon as possible after treatment.

- DO NOT wash, or use any liquids with, the Controller, Nebulizer Connection Cord, AC Power Supply, or Plug Converters.
- Use clear liquid soap designed for washing dishes. DO NOT use pearly, non-clear liquid dish soaps (eg, Ivory® or Dove®) or antibacterial liquid dish soaps. These may contain additives harmful to the equipment.

After your third and final treatment of the day, be sure to disinfect the Altera Nebulizer Handset.

[See Sample Dosing Schedule on other side.](#)

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## How to clean and disinfect your Altera Nebulizer Handset (cont'd)

As with any nebulizer, you will need to clean and disinfect your Altera Handset.

1. **Be sure to clean your Altera Handset after each use.**
2. **Disinfect it at the end of every treatment day.**

Follow the simple steps below to familiarize yourself with the simple process.

### Start by disassembling your Altera Handset

1. Disconnect the Handset from the Nebulizer Connection Cord.



Then proceed to disassemble the Altera Nebulizer Handset parts:

2. Twist and remove the Medication Cap from the Medication Reservoir.



3. Remove the Mouthpiece from the Aerosol Chamber.

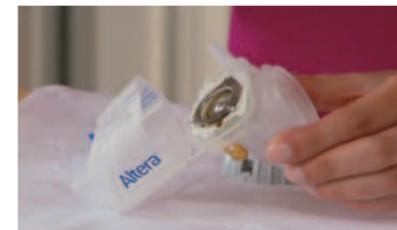


4. Gently pull up on the tab of the Medication Reservoir, releasing the Aerosol Chamber so you may open it.



Information continues in next column.

5. Remove the Inhalation Valve from the Aerosol Chamber.



6. Touching ONLY the plastic outer ring of the Aerosol Head, press the 2 flexible plastic tabs on the side of the Aerosol Head and remove it.



7. There is no need to disassemble the Medication Reservoir from the Aerosol Chamber for cleaning or disinfecting. Doing so may damage the hinge holding them together.

### Proceed to cleaning

1. Start by thoroughly rinsing each of the parts under warm, running tap water for approximately 10 seconds.
2. Rinse the Aerosol Head for at least 10 full seconds on each side. Thorough rinsing on both sides helps to prevent clogging and ensure proper operation. NEVER USE a brush or any other object.



3. Add a few drops of clear liquid dish soap to a clean bowl and add warm tap water.



4. Wash all parts and rinse thoroughly under warm, running tap water.

## Dry and store the parts

1. After rinsing, air-dry by placing the parts on a clean, lint-free towel.
2. After the parts are completely dry, place them in a bag for storage.
3. Reassemble the Altera Nebulizer Handset just prior to the next treatment. This helps to ensure that the silicone seals do not become warped over time.

## Disinfect the Altera Nebulizer Handset at the end of every treatment day

To reduce the risk of serious or fatal illness caused by contamination of the Altera Nebulizer Handset, you must also disinfect the Handset at the end of every treatment day. NOTE: The Altera Nebulizer Handset is strictly for single patient use only.

1. Clean the Altera Nebulizer Handset as described in cleaning section above.
2. Disinfect with a commercially available medical device disinfectant such as Control III®. Follow the disinfectant manufacturer's directions for use.



3. The Altera Nebulizer Handset may also be disinfected by boiling the parts, including the Aerosol Head, in a clean pot of distilled water for a full 5 minutes. **Do not boil in regular tap water, as it may damage the Aerosol Head.**



4. Allow parts to air-dry on a clean, lint-free towel.
5. Once the Altera Nebulizer Handset parts are completely dry, place them in a bag for storage.

Reassemble the Altera Nebulizer Handset just prior to the next treatment, helping to ensure that the silicone seals do not become warped over time.