

Step-by-step guide to your trial medication

What is Cayston?

Cayston (Aztreonam Lysine) is an inhaled antibiotic. Patients with bronchiectasis frequently get chest infections which are difficult to treat and can cause coughing, sputum production, breathlessness and tiredness. The purpose of this trial is to test whether Cayston is a good treatment for these symptoms.

We are comparing the health of participants treated with Cayston with the health of participants given a placebo, a substance that looks the same as Cayston but is not an active medicine (dummy medicine). You will not be able to choose whether you receive the Cayston medicine or the inactive medicine, this has been decided in a random way (a bit like tossing a coin but done by a computer). Neither have you, your nurse nor your doctor been told what you are prescribed.

How should I take Cayston/placebo?

Take Cayston/placebo exactly as prescribed by your trial team.

- A dose of Cayston/placebo for adults is 1 vial of Cayston/placebo, mixed with 1 ampule of saline (diluent) 3 times a day.
- Doses of Cayston/placebo should be taken 3 times a day with at least 4 hours between each dose.
- One course of treatment with Cayston/placebo means taking Cayston/placebo 3 times a day for 28 days, followed by 28 days off Cayston/placebo as directed by your trial team.

Before taking a dose of Cayston/placebo, 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 bronchiectasis, take them in this order:

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

Do not mix Cayston/placebo with any other medicines in your Altera Nebuliser System.

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

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

See detailed cleaning and disinfecting instructions later in this leaflet.

Sample Dosing Schedules

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

3 doses per day:
Breakfast
First Dose
Clean Nebuliser Handset
Afternoon
Second Dose
Clean Nebuliser Handset
Early Evening
Third Dose
Clean and disinfect nebuliser handsets used during the day

What should I do if I miss a dose?

- If you miss a dose of Cayston/placebo, you can still take all your daily doses as long as they are at least 4 hours apart.
- It is important that you finish taking the full 28-day course.
- Let your trial team know if you have missed any doses the next time you speak to them.

Possible side effects of Cayston

Cayston can cause serious side effects, these are rare but can include:

- Severe allergic reactions. Stop your treatment with Cayston seek medical advice right away if you have any symptoms of an allergic reaction, including:
 - Rash or swelling of your face
 - Throat tightness

You will receive your first dose of trial medication at your research visit and the research team will monitor you for any signs of side effects.

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 trial team 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 your treatment and tell your trial team if chest tightness develops during nebuliser use.

Common side effects of Cayston include:

- Cough
- Nasal congestion
- Wheezing
- Sore throat
- Chest discomfort
- Stomach area (abdominal) pain
- Vomiting
- Fever

Tell your trial team if you have any new or worsening symptoms while taking Cayston. Tell your trial team 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 trial team.

How should I store Cayston/placebo?

- You will be given enough vials of Cayston/placebo and ampules of saline for 28 days of treatment. There is 1 extra saline ampule per box in case some saline spills.
- Store Cayston/placebo in the refrigerator at 2 °C to 8 °C (36 °F to 46 °F) until needed.
- When you remove Cayston/placebo vials from the refrigerator, they may be stored at room temperature for up to 28 days. Do not use any Cayston/placebo that has been stored at room temperature for more than 28 days.
- The saline ampules can be stored at room temperature.

Cayston/placebo must be used with the Altera Nebuliser System

The Altera Nebuliser System has been designed specifically for use only with Cayston/placebo. Each dose should take about 2 to 3 minutes. It is important to remember:

- Do not use any other nebuliser for your Cayston/placebo treatment.
- Do not use any medication other than Cayston/placebo in the Altera Nebuliser System as this could result in potential incorrect dosage or overdoses of medication.
- Keep Cayston/placebo away from light.

- Do not use Cayston/placebo after the expiry date on the vial. Do not use the saline after the expiry date on the ampule.
- Use of other drugs could clog the Altera Aerosol Head, which may cause nebulisation of your Cayston/placebo treatment to be ineffective and shorten the useful life of the device.

Keep Cayston/placebo and all medicines out of the reach of children.

How to take Cayston/placebo with the Altera nebuliser system

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

Preparing your Cayston/placebo for inhalation

You will need the following supplies:

- 1 amber-coloured Cayston/placebo vial
- 1 ampule of saline (diluent)
- The Altera Nebuliser System

1. Mix (reconstitute) Cayston/placebo with the saline only when ready to take a dose. Take 1 amber vial of Cayston/placebo 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 the bin. 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 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/placebo 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. Start over again with a new vial of Cayston/placebo and a new ampule of saline.

6. Use Cayston/placebo right away after you mix with the saline.

Taking your Cayston/placebo 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/placebo 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)



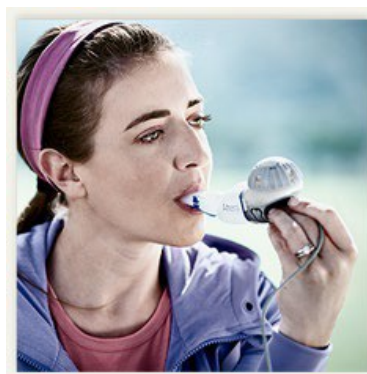
Figure 5



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. Please **keep** the empty vial and **return** to your trial team. The empty stopper, and saline ampule should be disposed of in the household bin upon completion of dosing.

Cayston/placebo must be used with the Altera Nebuliser System

The Altera Nebuliser System has been designed specifically for use only with Cayston/placebo. It is a lightweight, portable, and quiet way to deliver Cayston/placebo. Cayston/placebo is the only medication that has demonstrated efficacy and safety with the Altera Nebuliser 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 nebuliser for your Cayston/placebo treatment.
- Do not use any medication other than Cayston/placebo in the Altera Nebuliser System.
- Use of drugs other than Cayston/placebo in the Altera Nebuliser 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 Cayston/placebo treatment to be ineffective and shorten the useful life of the device.



How to clean and disinfect your Altera nebuliser handset

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

- DO NOT wash, or use any liquids with, the Controller, Nebuliser Connection Cord, AC Power Supply, or Plug Converters.
- Use clear liquid washing-up liquid designed for washing dishes. DO NOT use pearly, non-clear washing-up liquid or antibacterial washing-up liquid. These may contain additives harmful to the equipment.

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

As with any nebuliser, 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 familiarise yourself with the simple process.

Start by disassembling your Altera Handset

1. Disconnect the Handset from the Nebuliser Connection Cord.



Then proceed to disassemble the Altera Nebuliser Handset parts:

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



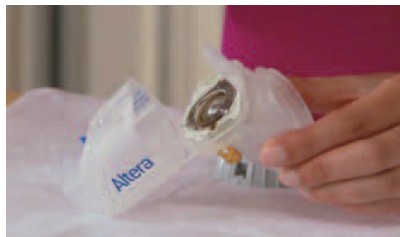
3. Remove the Mouthpiece from the Aerosol Chamber.



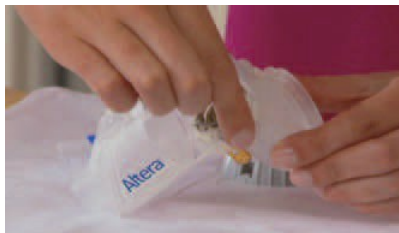
4. Gently pull up on the tab of the Medication Reservoir, releasing the Aerosol Chamber so you may open it.



5. Remove the Inhalation Valve from the Aerosol Chamber.



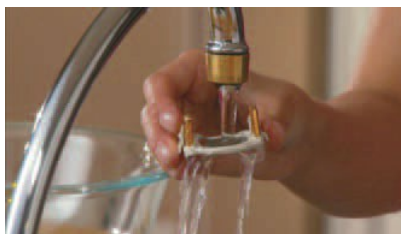
6. Touching ONLY the plastic outer ring of the Aerosol Head, press the 2 flexible plastic tabs on the side of the Aerosol Head and remove it.



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 washing-up liquid to a clean bowl and add warm tap water.



4. Wash all parts and
5. Rinse again under warm, running tap water.

Dry and store the parts

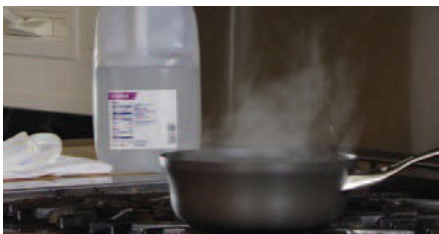
1. After rinsing, air-dry by placing the parts on a clean, lint-free towel.

2. After the parts are completely dry, place them in a bag for storage.
3. Reassemble the Altera Nebuliser Handset just prior to the next treatment. This helps to ensure that the silicone seals do not become warped over time.

Disinfect the Altera Nebuliser Handset at the end of every treatment day

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

1. Clean the Altera Nebuliser Handset as described in cleaning section above.



2. The Altera Nebuliser Handset should be disinfected by boiling the parts, including the Aerosol Head, in a clean pot of water for a full 5 minutes.
3. Allow parts to air-dry on a clean, lint-free towel.
4. Once the Altera Nebuliser Handset parts are completely dry, place them in a bag for storage.



Value of inhaled treatment with
aztreonam lysine in bronchiectasis

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

If you have any questions about using Cayston/placebo please contact your trial team: