How should I take CAYSTON?
- Take CAYSTON exactly as prescribed by your healthcare provider.
- 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 healthcare provider.
- CAYSTON is taken as a breathing treatment (inhalation) with the ALTERA Nebulizer System. Do not use any other nebulizer for your CAYSTON treatment.
- 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
- 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 healthcare provider.
- 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.
- Each treatment should take about 2 to 3 minutes. 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.

First Dose: Clean Nebulizer Handset (After breakfast)
Second Dose: Clean Nebulizer Handset (After school/work)
Third Dose: Clean Nebulizer Handset (Before bedtime)
Used During the Day

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.

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 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 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.

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, or throat tightness.
  - Trouble breathing right after treatment with CAYSTON (bronchospasm). Tell your healthcare provider right away if you experience shortness of breath with wheezing, or coughing and chest tightness. To decrease the chance of this happening, be sure to use your inhaled bronchodilator medicine before each treatment with CAYSTON.
- The most common side effects of CAYSTON include cough, nasal congestion, wheezing, sore throat, fever, chest discomfort, stomach area pain, and vomiting. These are not all the possible side effects of CAYSTON. Tell your healthcare provider if you have any new or worsening symptoms while taking CAYSTON and about any side effect that bothers you or that does not go away. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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 color-coded CAYSTON vial covered by a metal seal with a blue cap
- 1 ampule of saline (diluent)
- The ALTERA Nebulizer System

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. 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 (Figure 1). Pull the blue cap down to a flat (horizontal) position (where the bottom of the blue cap faces up) to prevent the metal seal for removal (Figure 2). Do not completely tear through the metal seal. 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 (Figure 3). When the metal seal opens, continue to slowly pull the blue cap in a counterclockwise direction until the metal seal is completely removed.
4. Safely throw away (dispose of) the metal seal in household garbage. Carefully remove but do not yet discard the rubber stopper.
5. 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.
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.
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.
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.
CAYSTON must be used with the ALTERA Nebulizer System

The ALTERA Nebulizer System has been designed specifically for use only with CAYSTON. It is a lightweight, portable, and quiet way to deliver CAYSTON. CAYSTON 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 CAYSTON treatment.
- Do not use any medication other than CAYSTON in the ALTERA Nebulizer System.
- Use of drugs other than CAYSTON 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 CAYSTON treatment to be ineffective and shorten the useful life of the device.

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.
2. Twist and remove the Medication Cap from the Medication Reservoir.
3. Remove the Mouthpiece from the Aerosol Head.
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 dish soap to a clean bowl and add warm tap water.
4. Gently pull up on the tab of the Medication Reservoir, releasing the Aerosol Chamber so you may open it.
5. Wash all parts and rinse thoroughly under warm, running tap water.
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.

Proper cleaning helps to disinfect the ALTERA Nebulizer Handset. Disinfect the ALTERA Nebulizer Handset just prior to the next treatment. This helps to ensure that the silicone seals do not become warped over time.

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.

How to clean and disinfect your ALTERA Nebulizer Handset

To reduce the 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 usepearly, soaaps or antibacterial liquid soap. 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.

Please see additional Important Safety Information and attached full Prescribing Information, including Patient Information.

How to clean and disinfect your ALTERA Nebulizer Handset (cont’d)

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