

**B. PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Cayston 75 mg powder and solvent for nebuliser solution

Aztreonam

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

1. What Cayston is and what it is used for
2. What you need to know before you take Cayston
3. How to take Cayston
4. Possible side effects
5. How to store Cayston
6. Contents of the pack and other information

#### **1. What Cayston is and what is it used for**

Cayston (aztreonam) is an antibiotic used to suppress chronic lung infection caused by the bacteria *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis. Cystic fibrosis, also known as mucoviscidosis, is a life-threatening inherited disease that affects the mucus glands of internal organs, especially the lungs, but also of the liver, pancreas, and the digestive system. Cystic fibrosis in the lungs leads to clogging them with thick sticky mucus. This makes it hard to breathe.

#### **2. What you need to know before you take Cayston**

##### **Do not take Cayston**

- **if you are allergic** to aztreonam or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor before taking Cayston:

- if you are **allergic to any other antibiotics** (such as penicillins, cephalosporins, and/or carbapenems)
- if you do not tolerate or have chest tightness from taking other inhaled medicines
- if you have **kidney problems**
- if you have ever **coughed up any blood**
- if you have ever had **low lung function tests**.

If any of these apply to you **tell your doctor** before using Cayston.

##### **Children and adolescents**

Cayston is not for use in children under the age of 6 years.

## Other medicines and Cayston

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

## Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There are no clinical data on the use of Cayston in pregnant women, therefore you should not take Cayston during pregnancy unless specifically discussed with your doctor.

If you plan to breast-feed ask your doctor for advice before taking Cayston. You can breast-feed during treatment with Cayston because the amount of Cayston likely to be passed to your child during breast-feeding will be extremely small.

## Driving and using machines

Cayston is not expected to affect your ability to drive or use machines.

## 3. How to take Cayston

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- **Take Cayston 3 times a day in repeated cycles of 28 days on therapy followed by 28 days off Cayston therapy.** Each of the three doses should be taken by inhalation at least four hours apart, using an Altera Nebuliser Handset. You can use either an eBase Controller or an eFlow rapid Control Unit with the Altera Handset.
- Each dose consists of one vial of Cayston mixed with one ampoule of solvent. Cayston needs to be mixed with a solvent before being inhaled through the Altera Nebuliser.

Put the prepared Cayston solution in the Altera Nebuliser Handset (see below). Each treatment takes about 2 to 3 minutes to inhale.

Use a bronchodilator before each dose of Cayston. Short acting bronchodilators can be taken between 15 minutes and 4 hours and long acting bronchodilators can be taken between 30 minutes and 12 hours prior to each dose of Cayston.

If you are using other inhaled therapies to treat cystic fibrosis, the recommended order of use is as follows:

1. bronchodilator
  2. mucolytics (a medicine that helps to dissolve the thick mucous produced in the lungs)
- and finally:
3. Cayston.

**Do not mix Cayston with any other medicines** in the Altera Nebuliser Handset.

- Do not put other medicines in the Altera Nebuliser Handset.
- Do not put the intravenous (injectable) form of aztreonam in the Altera Nebuliser Handset. Intravenous aztreonam is not suitable for inhalation.

## How to take Cayston using the Altera Nebuliser Handset

You will need the following:

- One amber-coloured vial of Cayston
- One plastic ampoule of solvent (0.17% w/v sodium chloride). The information that appears on the solvent ampoule is provided in English only (see section 6).
- An Altera Nebuliser Handset containing an Altera Aerosol Head connected to an eFlow Control Unit of the type 178 (eFlow rapid) or type 678 (eBase Controller).

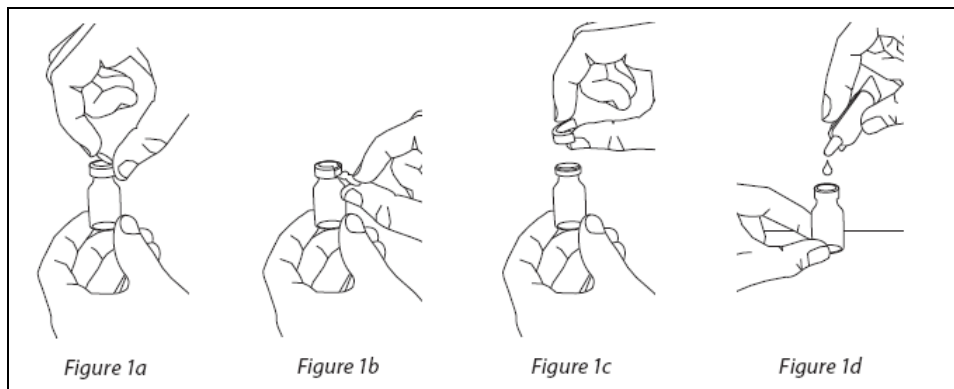
**You must use the Cayston specific Altera Nebuliser Handset containing an Altera Aerosol Head.** Do not try to take Cayston using any other type of nebuliser handset (including the eFlow rapid handset).

**Check that your nebuliser works properly** before starting your treatment with Cayston. Read the manufacturer's instructions for use provided with your Altera Nebuliser System carefully.

### Preparing your Cayston for inhalation

- Do not prepare Cayston until you are ready to administer a dose.
  - Do not use Cayston if you notice that the package has been tampered with.
  - Do not use Cayston if it has been stored outside a refrigerator for more than 28 days.
  - Do not use the solvent or prepared Cayston if it is cloudy or if there are particles in the solution.
1. **Take one amber vial of Cayston and one ampoule of solvent** from the box. Solvent ampoules must be separated by gently pulling them apart.
  2. **Gently tap the amber vial** containing the Cayston so that the powder settles at the bottom. This helps to ensure that you get the proper dose of medicine.
  3. **Open the amber vial** by lifting up the metal flap on the top (Figure 1a) and pulling down (Figure 1b) to carefully remove the entire metal ring and overcap from the vial (Figure 1c). Safely dispose of the ring. Carefully remove the rubber stopper.
  4. **Open the ampoule of solvent** by twisting off the tip. Squeeze out the contents completely into the vial (Figure 1d). Next, gently swirl the vial until the powder has completely dissolved and the liquid is clear.

**It's best to use Cayston immediately after you have made up the solution.** But, if you cannot use the prepared dose straight away, replace the stopper in the vial and store in a refrigerator. Use the prepared solution within 8 hours.



### Preparing the Altera Nebuliser to take your Cayston

1. **Make sure the Altera Nebuliser Handset** is on a flat, stable surface.

2. **Remove the medicine cap** by twisting anticlockwise.
3. **Pour all of the prepared Cayston from the vial** into the Altera Nebuliser Handset medicine reservoir (Figure 2a). Be sure to completely empty the vial. Gently tap the vial against the side of the medicine reservoir if necessary.
4. **Close the medicine reservoir** by aligning the tabs of the medicine cap with the slots on the reservoir. Press down and turn the cap clockwise as far as it will go (Figure 2b).

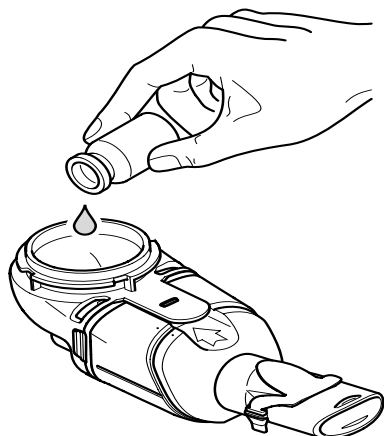


Figure 2a

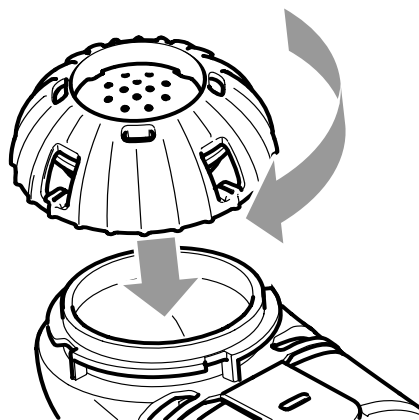


Figure 2b

### Using the Altera Nebuliser to take your Cayston

1. **Begin your treatment.** Sit in a relaxed, upright position. Hold the handset level and place the mouthpiece in your mouth and close your lips around it (Figure 3).

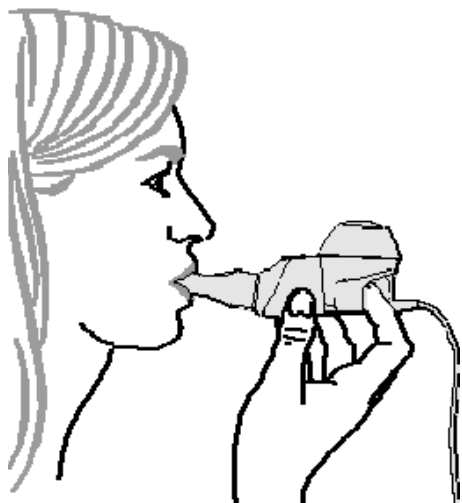


Figure 3

### Keep the handset level.

2. **Press and hold the On/Off button** on the Control Unit for a few seconds. You will hear one “beep” and the status light will turn green.
3. **After a few seconds**, an aerosol mist will begin to flow into the Aerosol Chamber of the Altera Nebuliser Handset. If aerosol mist does not begin to flow, please refer to the Altera manual for information.

4. **Breathe normally** (inhale and exhale) through the mouthpiece. Avoid breathing through your nose. Continue to inhale and exhale comfortably until the treatment is finished.
5. **When all of the medicine has been delivered**, you will hear a tone that means “treatment complete” (2 beeps).
6. **When treatment is complete**, open the medicine cap to ensure that all medicine has been used. A few drops of medicine may remain in the reservoir at the end of treatment. If there is more than a few drops of liquid left, replace the medicine cap and restart treatment.
7. **Once treatment is complete**, disconnect the Control Unit and take apart the Altera Nebuliser Handset for cleaning and disinfecting. For complete details on cleaning and disinfecting refer to the manufacturer’s instructions for use provided with your Altera Nebuliser Handset.

**What if I need to stop my treatment before I’ve finished?**

8. If for any reason you must stop the treatment before you have finished, press and hold the On/Off button for one full second. To re-start the treatment, press and hold the On/Off button for one full second and then restart the treatment.

**Replacing the Altera Nebuliser Handset**

The Altera Nebuliser Handset is designed to last for three 28-day courses of Cayston when used as directed. After this time replace your Altera Nebuliser Handset, including the aerosol head. If you notice that the performance has changed before this time (for instance, if it takes longer to produce a mist, more than 5 minutes), please refer to the Altera Nebuliser instructions for use.

**If you take more Cayston than you should**

If you have taken more Cayston than you should, talk to a doctor or pharmacist immediately.

**If you forget to take Cayston**

If you miss a dose, you can still take all 3 daily doses as long as they are at least 4 hours apart. If you can’t leave a gap of 4 hours just skip the missed dose.

**If you stop taking Cayston**

Do not stop taking Cayston without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get a rash, tell your doctor immediately** because this could mean that you have an allergic reaction to Cayston.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

not known (frequency cannot be estimated from the available data).

#### Very common side effects

- Cough
- Blocked nose
- Wheezing
- Sore throat
- Shortness of breath
- High temperature. This may be more common in children than in adults.

#### Common side effects

- Difficulty breathing
- Chest discomfort
- Runny nose
- Coughing up blood
- Rash
- Joint pain
- Lower lung function test results

#### Uncommon side effects

- Joint swelling

The following side effects have been observed after the use of aztreonam for injection, but not after taking Cayston: swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing, sweating, skin irritation and flaking, itchy rash, flushing, small red spots and very rarely, blistering of the skin. All these may be signs of an allergic reaction.

As an inhaled medicine, Cayston could cause you to cough and this could lead to coughing up blood. If you have ever coughed up blood you should only use Cayston if your doctor thinks the benefit of taking this medicine outweighs the risk of coughing up blood.

You may get a temporary lowering of lung function test result during treatment with Cayston, but this is typically not a lasting effect.

Tell your doctor if you have any of these effects.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **5. How to store Cayston**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label, solvent ampoule and the carton. The expiry date refers to the last day of that month.

Powder vial and solvent ampoule:

Store in a refrigerator (2°C - 8°C). The unopened vials may also be stored outside the refrigerator but below 25°C for up to 28 days.

Use this medicine immediately after preparation. If not used immediately, the prepared solution must be stored at 2°C - 8°C and used within 8 hours. Do not prepare more than one dose at a time.

Do not use this medicine if you notice that the package has been tampered with.

Do not use this medicine if it has been stored outside a refrigerator for more than 28 days.

Do not use the solvent or prepared medicine if it is cloudy or if there are particles in the solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Cayston and the solvent contain

- The powder vial contains 75 mg aztreonam (which is the active substance) as lysine.
- The solvent ampoule contains water for injections and sodium chloride. The ampoule is imprinted in English only. The information that appears on the ampoule is presented below:

Solvent for Cayston Sodium Chloride 0.17%
Inhalation use only
1 ml
GILEAD SCIENCES

### What Cayston looks like and contents of the pack

Cayston is a sterile, white to off-white, lyophilised powder.

Cayston is contained in a 2 ml amber glass vial with a grey rubber stopper and aluminium tear-off overseal.

The 1 ml solvent is contained in a plastic ampoule.

Each 28-day pack of Cayston contains 84 vials of lyophilised Cayston and 88 solvent ampoules. The four additional solvent ampoules are provided in case of spillage.

The following pack sizes are available:

- 28-day pack of Cayston
- Pack containing one 28-day pack of Cayston plus one Altera Nebuliser Handset

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder:

Gilead Sciences International Limited  
Granta Park  
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#### Manufacturer:

Gilead Sciences Limited  
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**This leaflet was last revised in 12/2012.**

**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.