

**Patient leaflet in accordance with the pharmacists' regulations (preparations) -
1986**

This medicine is to be supplied upon physician's prescription only

Cayston®

Powder and solvent for nebuliser solution

Active ingredients - each vial contains Aztreonam 75mg

Inactive ingredients and allergens: See section 6 "*Additional information*".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for treating your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

The medicine is not intended for children under the age of 6 years.

1. What is Cayston intended for?

Cayston is used to suppress chronic lung infection caused by the bacteria *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis.

Therapeutic group: antibiotic.

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. Before taking Cayston

X Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).

! Special warnings regarding the use of the medicine

Before using Cayston, tell your physician if:

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

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

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.

Children

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 other medicines, including non-prescription medicines, vitamins, herbal remedies or dietary supplements.

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 or pharmacist 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 dosage and treatment will be determined only by the physician. The recommended dose is usually:

- **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.

Do not exceed the recommended dose.

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 with a blue cap.
- 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. Follow Step A to D in Figure 1 below to open the amber vial:

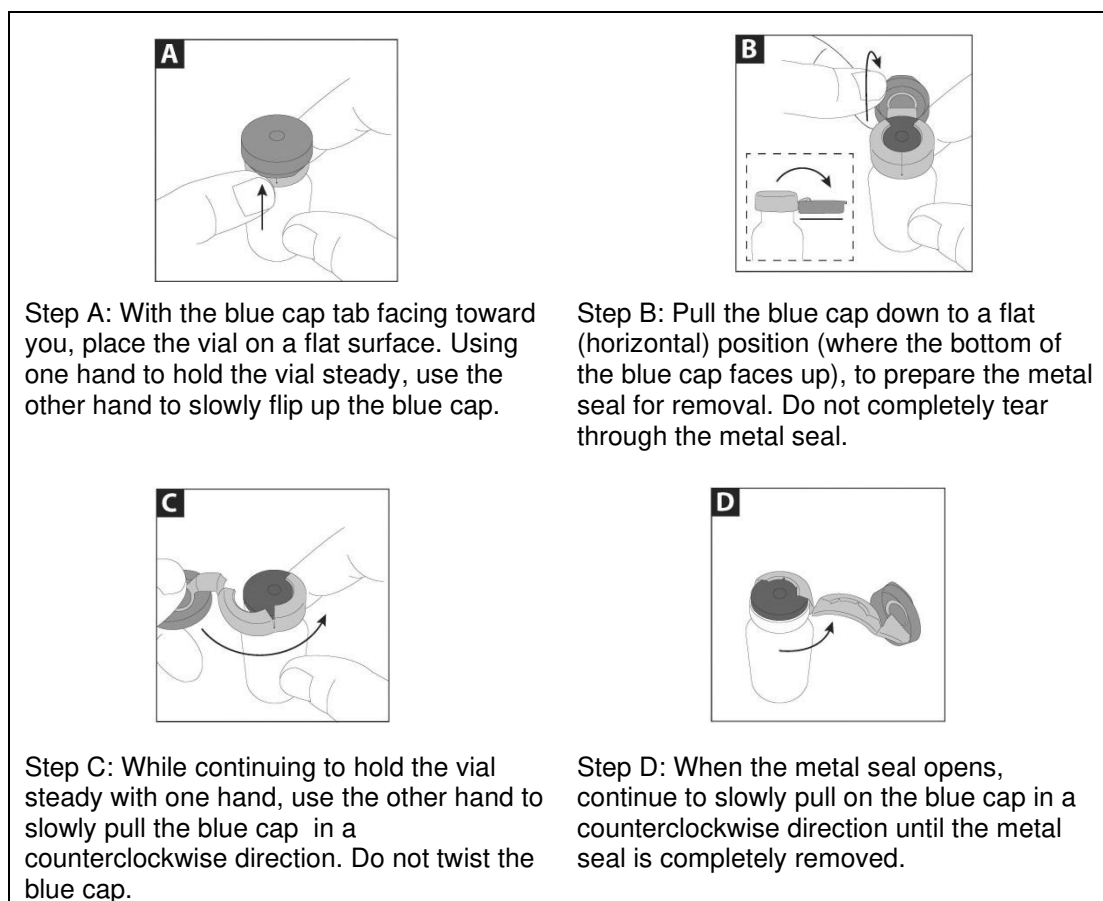


Figure 1

4. Safely dispose of the metal seal. Carefully remove (but do not yet discard) the rubber stopper.

5. **Open the ampoule of solvent** by twisting off the tip. Squeeze out the contents completely into the vial (Figure 2). 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.



Figure 2

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 3a). 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 3b).

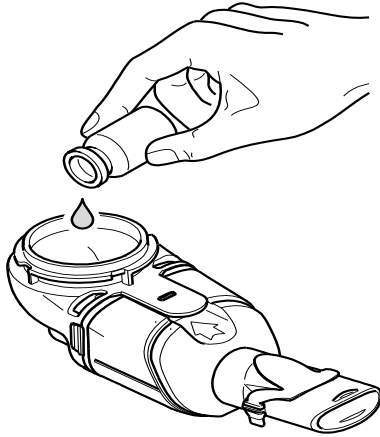


Figure 3a

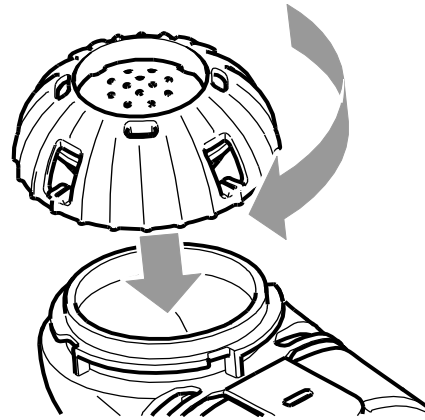


Figure 3b

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 4).

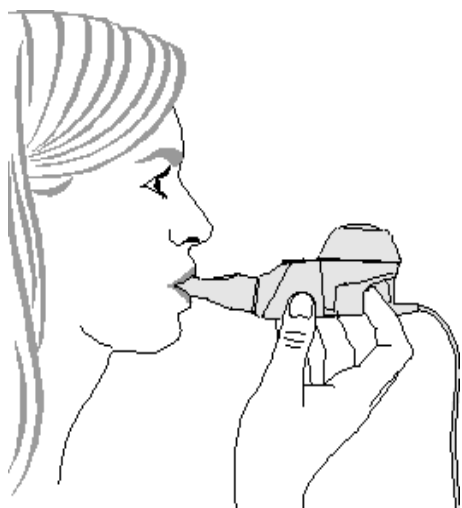


Figure 4

Keep the handset level.

2. **Press the On/Off button** on the Control Unit. You will hear one “beep”.
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

Refer to the Altera Nebuliser Handset instructions for use for guidance on when to replace the handset. 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 have accidentally taken more Cayston than you should or if a child accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the medicine with you.

If you forget to take Cayston 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.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician or the pharmacist.

If you stop taking Cayston

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

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of Cayston may cause side effects in some of the patients. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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

Additional side effects

Very common side effects (affects more than 1 user in 10)

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

Common side effects (affects 1 to 10 users in 100)

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

Uncommon side effects (affects 1 to 10 users in 1,000)

- 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.

Tell your doctor if you have any of these effects.

If you get any side effect or if any of the side effects get worse, or when you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting of side effects

You can report any side effects to the Ministry of Health by clicking on the link "Report side effects due to medical treatment" that is located on the Ministry of Health homepage (www.health.gov.il) which redirects to the online form for reporting side effects, or by clicking on the link: <https://sideeffects.health.gov.il>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cayston?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use this medicine after the expiry date (exp. date) appearing on the vial label, solvent ampoule and the carton. The expiry date refers to the last day of that month.
- Store powder vial and solvent ampoule in a refrigerator (2°C-8°C): This temperature range is commonly found in a home refrigerator. The unopened vials may also be stored outside the refrigerator but below 25°C for up to 28 days.
- Store in the original package.
- 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 discard the medicine to the wastewater or household waste. Consult the pharmacist about how to dispose of the medicine. These measures will help in environmental protection.

6. Additional information

In addition to the active ingredient the medicine also contains:

Powder: Lysine Monohydrate.

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
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What does the medicine look like and what is the content of the package:

Cayston is a white to off-white powder and solvent for nebulizer solution. Cayston is contained in a 2 ml amber glass vial with a grey rubber stopper and aluminium tear-off overseal with a blue cap.

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:

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

Registration holder:

Gilead Sciences Israel Ltd.
4 HaHarash Street
Hod Hasharon Business Park,
Hod Hasharon
4524075
Israel

Manufacturer:

Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 34026

For simplicity and ease of reading, this leaflet was phrased in the masculine. Nevertheless, the medicine is intended for both sexes.

Revised in August 2024 in accordance with MoH guidelines.

Reference: EU label from July 2024.

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