

Colobreathe[®]

(colistimethate sodium)

INSTRUCTIONAL GUIDE

This booklet has been developed by Essential Pharma and is intended for patients who are prescribed Colobreathe and their caregiver(s). It should be used in conjunction with the Colobreathe Patient Information Leaflet which should be referred to for full information.



Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in the package leaflet. You can also report side effects in the UK directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. In the Republic of Ireland, you can report side effects directly via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.



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INTRODUCTION

You have been provided with this booklet because you, or someone you care for, has been prescribed Colobreathe, a medicine used for the management of persistent pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged 6 years and older.

This booklet will provide you with information on what Colobreathe is and instructions on how it should be administered using the Turbospin inhaler. If you have any further questions, please consult with your doctor, pharmacist or nurse.



Packaging may vary

ABOUT Colobreathe

How does Colobreathe work?

Pseudomonas aeruginosa is a very common bacterium that infects almost all cystic fibrosis patients at some point in their lives. It is crucial to control this type of infection, as it can cause damage to the lungs.

The active ingredient in Colobreathe is colistimethate sodium, an antibiotic from the polymyxin class which works by damaging bacterial cell membranes. When Colobreathe is inhaled into the lungs it targets *Pseudomonas aeruginosa*, killing the bacteria and helping to control the infection.

The Colobreathe pack

There are three main elements included within the Colobreathe pack:

- The **blister packs**, which provide a total of 56 hard capsules, sufficient for 4 weeks of use (the capsules contain the actual medicine)
- The **Turbospin inhaler**, a device that ensures the medicine is effectively delivered into the lungs via inhalation
- The **Patient Information Leaflet**, a document providing you with everything you need to know about Colobreathe

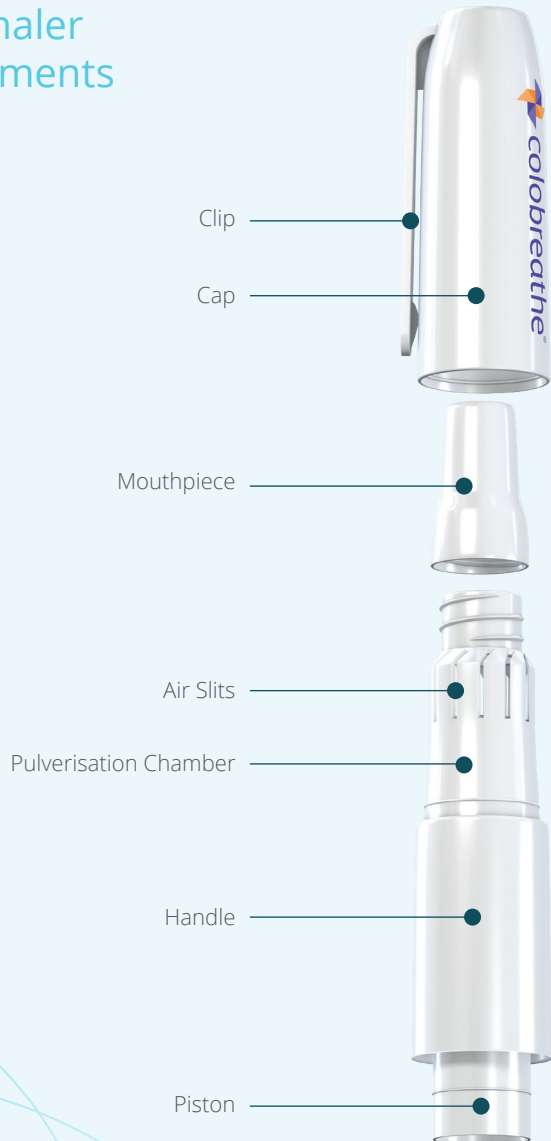


Packaging may vary

THE TURBOSPIN inhaler

Colobreathe should only be used with the Turbospin inhaler, provided in each pack.
Do not attempt to take the medicine in any other way, such as swallowing.

The Turbospin inhaler
has seven key elements



DIRECTIONS for use

Dosing

Each capsule of Colobreathe contains a fine powder and contains enough medicine for one dose (approximately 125 mg of colistimethate sodium). One dose should be inhaled twice daily, ideally as close to 12 hours apart as possible (for example, one in the morning at 08:00 and the other in the evening at 20:00).

To ensure proper administration of the medicine, a healthcare professional should demonstrate how to use the inhaler and supervise the first dose.

If other treatments are being taken for cystic fibrosis, they should generally be taken in the following order:

- 1 Inhaled bronchodilators
- 2 Chest physiotherapy
- 3 Other inhaled medicines
- 4 Then Colobreathe

However, the order of the treatments should be confirmed with a healthcare professional – always use Colobreathe as advised by your doctor.

If you/your child forget to take a dose of Colobreathe then you/your child should take your missed dose as soon as you/your child remember. You/your child must not take 2 doses within 12 hours. Carry on from there as instructed.

If you/your child use more Colobreathe than you/your child should, or have accidentally swallowed the capsule, contact your doctor immediately for advice.

Steps for administration

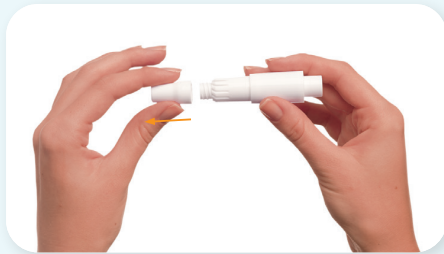
Colobreathe has a shelf life of three years, but it is important to check the expiry date before each dose, which is stated on the box and blister after EXP. The expiry date refers to the last date of that month. **Do not** use Colobreathe after the expiry date.

Taking Colobreathe using the Turbospin inhaler:



1

Remove the cap. It comes away with a gentle pull.



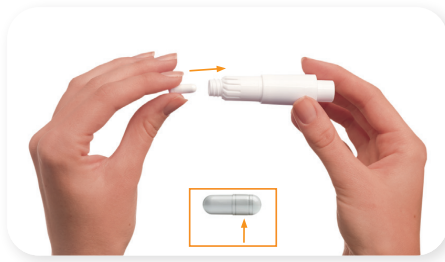
2

Unscrew the mouthpiece, exposing the chamber of the Turbospin inhaler.



3

Remove a single capsule from the blister pack by peeling away the foil. Never push the capsule out of the blister pack. Once you have removed the capsule it must be used immediately.



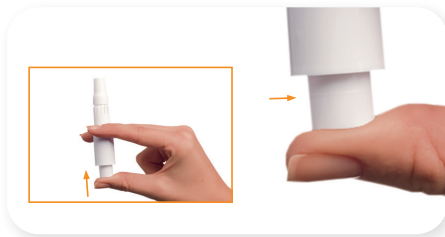
4

Gently insert the capsule into the chamber with the widest end first. No force is required.



5

Now replace the mouthpiece by screwing it back into place.



6

To pierce the capsule, hold the inhaler with the mouthpiece upright and gently push the piston until the visible line is reached – you will feel resistance at this point, and this will lock the capsule in place ready for piercing. Hold that position before continuing to follow through with the piercing.

Now with the capsule locked in place, continue pushing the piston as far it will go then release. The capsule is now pierced, and the contents can be inhaled. You may see a small amount of powder released from the capsule chamber after the capsule is pierced, this is normal.

Do not pierce the capsule more than once, as this will increase the chances of the capsule breaking into smaller pieces.



7

Breathe out slowly and place the mouthpiece between your lips and teeth, ensuring there is a seal. Take care not to cover the air slits with your fingers or mouth during the inhalation.

8

Then, breathe in slowly and deeply through your mouth at a pace slow enough so you can hear or feel the capsule spinning. During inhalation small pieces of the capsule may enter your mouth or airways – the capsule is made of gelatine, which is harmless to humans if inhaled or ingested.

If you do not hear the capsule moving, it may be stuck in the compartment. If this occurs, you can loosen the capsule by gently tapping the chamber of the inhaler. **Do not** try to loosen the capsule by repeatedly pressing the piston. If the capsule cannot be loosened and the powder cannot be inhaled, dispose of the capsule and any powder remaining and use another.

9

Following inhalation, remove the Turbospin inhaler from your mouth and hold your breath for about 10 seconds, or for as long as is comfortable. Then breathe out slowly.

10

Repeat steps 7 to 9 until the capsule is empty. You can check this by unscrewing the mouthpiece and checking the capsule.

11

Once all the contents have been inhaled, rinse your mouth out well with water and spit it out (**do not** swallow the water). Rinsing may reduce the risk of developing oral fungal super-infection during treatment and may also reduce the unpleasant taste associated with colistimethate sodium.

12

To discard the empty capsule, unscrew the mouthpiece and remove it from the chamber. The inhaler must now be cleaned (please refer to next section).

CLEANING the Turbospin inhaler

Following removal of the empty capsule from the chamber, the Turbospin inhaler should be cleaned. This should be done after every dose by following the steps below:

1. Deeply press the piston a few times whilst keeping the chamber upside down.
2. Then, clean the chamber using a dry, soft tissue or a dry cotton bud. **Do not** use water, or any other form of moisture. **Do not** blow into the chamber, as this will add moisture which can clog up the chamber.
3. Finally, screw the mouthpiece firmly back in place and put the cap back on.
The Turbospin inhaler is now ready to be used for your next dose.

STORAGE and disposal

Colobreathe should be kept out of the sight and reach of children, in its original packaging, and at room temperature until immediately before use to prevent exposure to moisture.

Do not put Colobreathe in the fridge or exceed temperatures above 25°C.

In the case that any of the capsules in the blister packs become accidentally exposed, these capsules should be discarded. To help protect the environment, medicines should not be discarded via wastewater or household waste. Ask a pharmacist how to throw away medicines you no longer/cannot use.

The Turbospin inhaler should also be discarded after the completion of the Colobreathe pack, as a new device will be provided along with another pack.

SAFETY information

Possible side effects

Like all medicines, Colobreathe may cause side effects, although not everyone will experience them. When starting Colobreathe the user may experience a cough, breathlessness, tightness of chest or wheezing. The number of these side effects may reduce as you continue to use the inhaler or your doctor may prescribe other medicines to use before taking Colobreathe.

VERY COMMON SIDE EFFECTS

(may affect more than 1 in 10 people taking Colobreathe) include:

Difficulty breathing

Cough, throat irritation

Hoarse or weak, or even loss of voice

Unpleasant taste

COMMON SIDE EFFECTS

(may affect up to 1 in 10 people taking Colobreathe) include:

Headache

Ringing or buzzing noises in the ear, problems with balance

Coughing up blood, wheezing, chest discomfort, asthma, productive cough (brings up mucus), infection of the lungs, lung crackles (your doctor would hear this when listening to your lungs with a stethoscope)

Vomiting, nausea

Changes in how your lungs function (found by testing)

Joint pains

Lack of energy, tiredness

Raised temperature

For a full list of side effects, please refer to the Patient Information Leaflet.

Allergic reactions

An allergic reaction with Colobreathe is possible. A serious allergic reaction may typically cause rashes, swelling of the face, tongue and neck, inability to breathe due to narrowing of the airways and loss of consciousness.

If signs of an allergic reaction are seen, please seek urgent medical attention.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet. You can also report side effects in the UK directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. In the Republic of Ireland, you can report side effects directly via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

NOTES





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MAT-COL-IE-0002-0725
July 2025

