



Healthcare Professional and Patient Guide with Instructions for Use

This instructional leaflet is intended for Healthcare Professionals who prescribe COLOBREATHE® (Colistimethate Sodium) and for Patients who are prescribed COLOBREATHE® and their Caregiver.

Teva UK Limited, Ridings Point,
Whistler Drive, Castleford WF10 5HX

Version 1

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CLB-GB-NP-00012

Reporting of side effects

For Patients:

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 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.

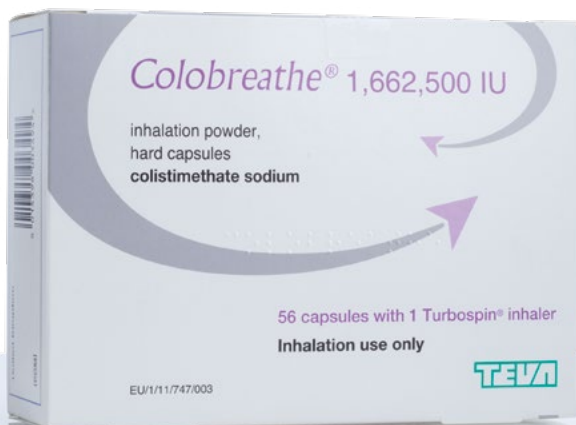
By reporting side effects you can help provide more information on the safety of this medicine.

For Healthcare Professionals:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events may also be reported to Teva UK Limited via email to medinfo@tevauk.com or via phone on +44 (0) 207 540 7117.



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Introduction

Colobreathe is indicated for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis aged 6 years and older¹.

In this booklet, you will find detailed information on how to load the Colobreathe Turbospin inhaler, how to inhale the medicine and inspect and clean the device.

About Colobreathe

There are two elements to Colobreathe medicine: the capsule that contains the actual medicine and the Turbospin inhaler, a device that ensures the medicine is delivered right into the lungs where it is needed¹.



Contents of the pack

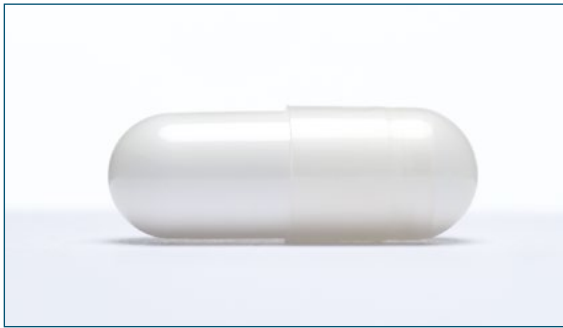
Each treatment pack contains capsules packed in blister strips and one Turbospin inhaler. There is one pack size available:

- 56 capsules and one Turbospin inhaler – enough for 4 weeks use¹.



How to use Colobreathe

The Colobreathe medicine should be inhaled using the Turbospin inhaler – one capsule in the morning and another in the evening. Ideally there should be a 12-hour gap between doses. To ensure proper administration of the medicine, a healthcare professional should demonstrate how to use the inhaler and supervise the first dose¹.



Each capsule is filled with enough medicine for one dose (approximately 125mg of colistimethate sodium). The medicine is a very fine powder designed for inhalation¹.

Always use Colobreathe exactly as advised by the healthcare professional¹.

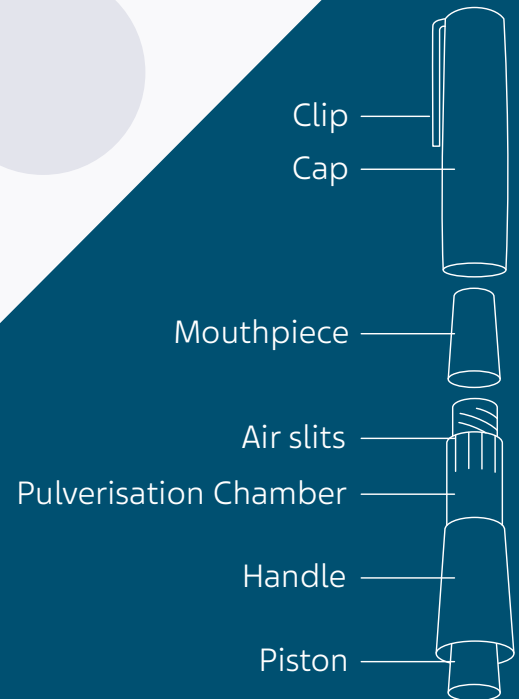
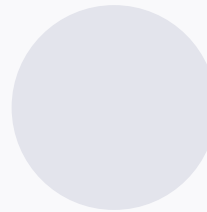
The Turbospin inhaler

Colobreathe medicine should only be taken using the Turbospin inhaler¹.

Do not attempt to take the medicine in any other way such as swallowing¹.

The Turbospin inhaler has six key elements²:

- a piston that is used to pierce the capsules
- the handle of the Turbospin inhaler
- the pulverisation chamber
- air slits
- mouthpiece
- a cap with a clip

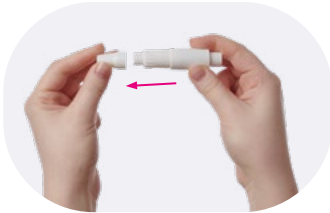


Taking Colobreathe using the Turbospin inhaler



01

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



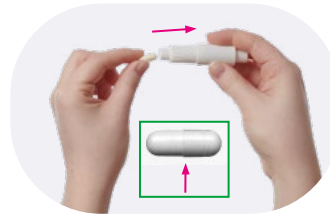
02

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



03

Remove a single capsule from the blister pack. Once you have removed the capsule it must be used immediately.



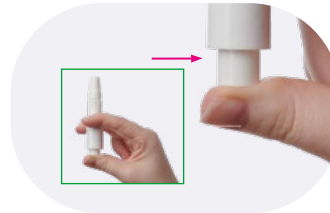
04

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



05

Now replace the mouthpiece by screwing it back into place.



06

To pierce the capsule:

- Hold the inhaler with the mouthpiece upright, gently push the piston upwards 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.

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 as it will go and then release.

- The capsule is now pierced and the contents can be inhaled.

Do **not** pierce the capsule more than once. You may see a small amount of powder released from the capsule chamber after the capsule is pierced, this is normal.



07

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

08

Then, breathe in slowly and deeply through your mouth at a rate sufficient for you to hear or feel the capsule spinning.

09

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

If you do not hear the capsule spinning, the capsule 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 broken capsule and any powder remaining in it and use another.

11

Inhale the medicine again by repeating Steps 7 and 8 to ensure you have emptied the capsule.

12

You can check whether the capsule is empty by unscrewing the mouthpiece and checking the capsule. If it is not empty, repeat steps 7, 8 and 9 until you have inhaled all of the contents.

13

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

14

When the capsule is empty, unscrew the mouthpiece, then remove and discard the empty capsule.

Additional information when using Colobreathe

As you breathe in slowly, you suck air through the body of the Turbospin inhaler into the capsule chamber. The tiny particles of medicine in the capsule are picked up by the airflow and carried on down your airway into your lungs.

Occasionally, very small pieces of the capsule shell can get into your mouth or airways.

- If this happens, you may be able to feel these pieces on your tongue or in your airways.
- The capsule shell is made of gelatin, which is harmless to humans if swallowed or inhaled.
- The chances of the capsule breaking into pieces are increased if the capsule is pierced more than once during Step 6.

Cleaning the Turbospin inhaler

You should clean your Turbospin inhaler after each dose².

Deeply press the piston a few times whilst keeping the chamber upside down².

Then, clean the chamber using a soft tissue or cotton bud. **Do not** use water².

Finally, screw the mouthpiece firmly back in place, put the cap back on. The Turbospin inhaler is now ready to be used for your next dose².

Discard the Turbospin inhaler after completion of a treatment pack¹.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use².

Side effects

Like all medicines, Colobreathe may cause side effects although not everyone will experience them¹.

One very common side effect (may affect more than 1 in 10 people) is an unpleasant taste which may be experienced immediately after inhalation. So it is important to rinse the mouth out with water after each dose¹.

Other very common side effects include cough or throat irritation, dyspnoea (difficulty in breathing) and dysphonia (hoarseness) or even loss of voice^{1,2}.

Common side effects (may affect up to 1 in 10 people) include^{1,2}:

- Headache
- Tinnitus (ringing or buzzing noises in the ear)
- Balance disorder (problems with balance)
- Haemoptysis (coughing up blood), wheezing, chest discomfort, asthma, a productive cough
- Lower respiratory tract infection (infection of the lungs), lung crackles
- Forced expiratory volume decreased (changes in lung function)
- Vomiting or nausea.
- Arthralgia (joint pains)
- Asthenia (lack of energy), fatigue (tiredness)
- Pyrexia (raised temperature)

The number of these side effects may reduce as you continue to use your Turbospin inhaler².

For a list of all side effects, the healthcare professional should refer to the Colobreathe Summary of Product Characteristics for a full list of undesirable effects.¹ The patient should look at the in-pack patient information leaflet or ask a healthcare professional².

An allergic reaction is possible with Colobreathe. If any signs of an allergic reaction are experienced (typically rashes, swelling of the face, tongue and neck, inability to breathe) you should seek urgent medical attention².

If any other side effects are experienced, a healthcare professional or pharmacist should be consulted².

It is possible whilst using Colobreathe that dizziness, confusion or problems with sight (visual disturbances) may be experienced. Do not drive or use any machines until the symptoms have gone away^{1,2}.

If other treatments are being taken for cystic fibrosis, they should be taken in the following order¹:

- inhaled bronchodilators
- chest physiotherapy
- other inhaled medicines
- then Colobreathe

However, the order of the treatments should be confirmed with a healthcare professional².

Patients please note: If you have any. If you have any concerns or are unsure about any aspect of your medicine, you should always consult your healthcare professional or pharmacist².

Additional information for Healthcare Professionals

Bronchospasm or coughing may occur on inhalation. These reactions usually disappear or significantly diminish with continued use and may be ameliorated by appropriate treatment with beta₂-agonists prior to or following dry powder colistimethate sodium inhalation. If bronchospasm or coughing remain problematic, withdrawal of treatment should be considered¹.

Storing Colobreathe

Once, the dose has been taken and the inhaler cleaned, make sure to put the pack away out the sight and reach of children²

Do not store above 25°C².

Store in the original package until immediately before use in order to protect from moisture².

If you accidentally peel back the foil, and any capsules become exposed, please discard these capsules².

Do not use this medicine after the expiry date, which is stated on the outer carton and blister after EXP. The expiry date refers to the last date of that month².

References:

1. Colobreathe Summary of Product Characteristics, Teva UK Limited
2. Colobreathe Package Leaflet, Teva UK Limited

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The Teva logo consists of the word "teva" in a bold, lowercase, blue sans-serif font. The letter "v" is stylized with two green leaf-like shapes extending upwards from its top bar.