

COLOBREATHE®
(COLISTIMETHATE SODIUM)

**HEALTHCARE
PROFESSIONAL GUIDE
AND INSTRUCTIONS
FOR USE**

Teva Pharmaceuticals Ireland,
Digital Office Centre Swords,
Suite 101 – 103, Balheary
Demense, Balheary Road, Swords,
Co. Dublin, K67E5AO.

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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 older.¹

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

About Colobreathe

There are two elements to Colobreathe: the capsule that contains the active pharmaceutical ingredient and the Turbospin inhaler, a device that ensures the patient's medicine is delivered right into their lungs where it is needed.¹

Contents of the pack

The capsules are packed in blister packs supplied in cartons containing:

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

Using Colobreathe

Patients should inhale the Colobreathe medicine using the Turbospin inhaler – one capsule in the morning and another in the evening. Ideally there should be a 12-hour gap between doses.¹

To ensure proper administration of the medicine, show the patient how to use the inhaler and supervise their first dose.¹



Each capsule contains approximately 125mg of colistimethate sodium as a fine powder designed for inhalation.¹

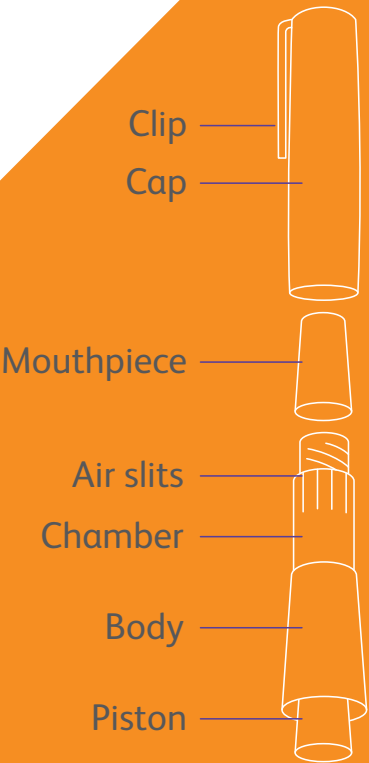
The Turbospin inhaler

Patients should only take their Colobreathe medicine using the Turbospin inhaler.¹

Capsules are for inhalation only. Patients should not attempt to take the medicine in any other way¹

The Turbospin inhaler has six key elements:²

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



Taking Colobreathe using the Turbospin inhaler

The following instructions should be adhered to by the patient when taking Colobreathe:¹

1.



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

2.



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

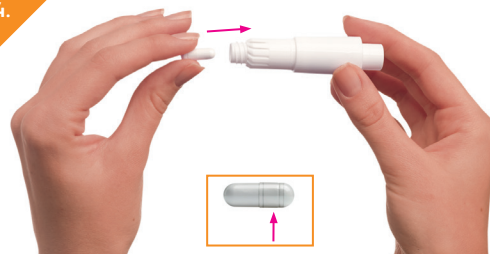
3.



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

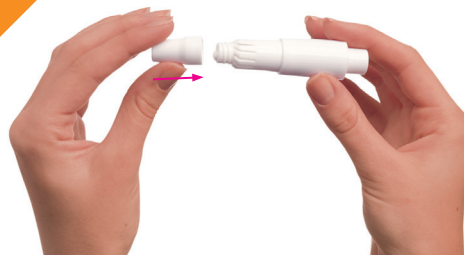
Never try and push the capsule through the foil as this may break the capsule and spill some of the contents.

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, 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.
- 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.



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.

8.

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

9.

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 the patient breathes in slowly, they 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 their airway into their lungs.

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

- ▶ If this happens, they may be able to feel these pieces on their tongue or in their 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

Patients should be instructed to clean their Turbospin inhaler after each dose.²

To do this, they should push the piston in as far as possible while keeping the chamber turned upside down.²

Then they can clean the chamber with a soft tissue or cotton bud.²

Patients should **never** use water to clean the device.²

Finally, they can screw the mouthpiece firmly back onto the device and replace the cap. The Turbospin inhaler is now ready to be used for their next dose.²

Patients should discard the Turbospin inhaler after they have completed their treatment pack.¹

Side effects

Like all medicines, Colobreathe may cause side effects although not every patient will experience them.¹

One very common side effect (that may affect more than 1 in 10 people) is an unpleasant taste, which may be experienced immediately after inhalation. So it is important that a patient rinses their mouth out with water after each dose.¹

Other very common side effects include dyspnoea, cough, dysphonia or throat irritation.¹

Common side effects (that may affect up to 1 in 10 people) include:¹

- ▶ headache, balance disorder
- ▶ haemoptysis, bronchospasm, asthma, wheezing, chest discomfort, lower respiratory tract infection, productive cough, lung crackles
- ▶ vomiting, nausea
- ▶ arthralgia
- ▶ pyrexia, asthenia, fatigue
- ▶ forced expiratory volume decreased

The number of these side effects may reduce as patients continue to use their Turbospin inhaler.²

Please see Colobreathe Summary of Product Characteristics for a full list of undesirable effects.¹

An allergic reaction is possible with Colobreathe. If a patient experiences signs of an allergic reaction they should be advised to seek urgent medical attention.²

Patients should also be warned not to drive or operate machines if they experience neurological side effects such as dizziness, confusion or visual disturbances.¹

If other treatments are being taken, they should be taken in the following order:¹

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

Additional information

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, you should consider withdrawal of treatment.¹

Reporting of side effects

Any suspected adverse reactions to Colobreathe should be reported to Teva via email to **safety.ireland@teva.ie** or by telephone to **+44 207 540 7117**.

You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance

Website: www.hpra.ie

Storing Colobreathe

Patients should ensure Colobreathe is not stored above 25°C.¹

Instruct them to store in the original package until immediately before use in order to protect from moisture.¹

If a patient accidentally peels back the foil and exposes any capsules they should discard these capsules.²

Patients should not use after the expiry date, which is shown on the outer carton and blister packs.²

References:

1. Colobreathe Summary of Product Characteristics
Teva B. V. Swensweg 5, 2031 GA Haarlem Netherlands
2. Colobreathe Package Leaflet Information for the User
Teva B. V. Swensweg 5, 2031 GA Haarlem Netherlands

