

COLOBREATHE[®]
(COLISTIMETHATE SODIUM)

**PATIENT GUIDE AND
INSTRUCTIONS FOR USE**

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Introduction

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 your Colobreathe medicine: the capsule that contains the actual medicine and the Turbospin inhaler, a device that ensures your medicine is delivered right into your lungs where it's needed.

Contents of the pack

Each treatment pack contains capsules packed in blister strips and one Turbospin inhaler. There are two pack sizes:

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

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. Your healthcare professional will supervise your first dose of the medicine.



Each capsule is filled with enough medicine for one dose. The medicine is a very fine powder designed for inhalation.

Always use Colobreathe exactly as your healthcare professional has told you.

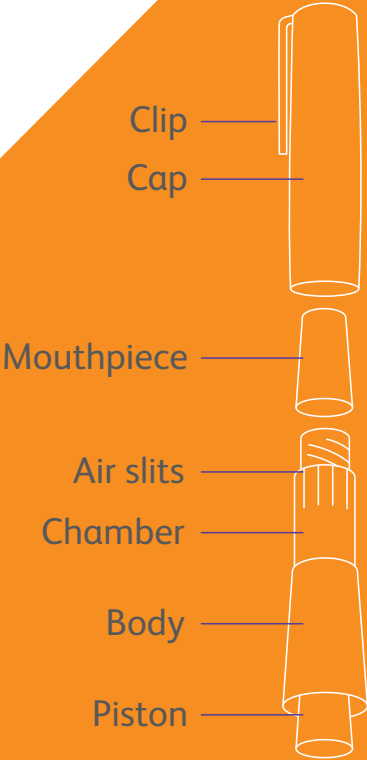
The Turbospin inhaler

You should only take your Colobreathe medicine using the Turbospin inhaler.

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

The Turbospin inhaler has six key elements:

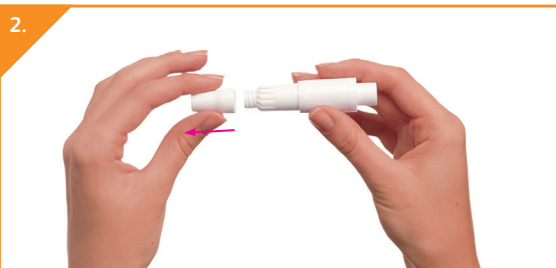
- ▶ a piston that is used to pierce the capsules
- ▶ the body of the Turbospin inhaler
- ▶ the capsule chamber
- ▶ air slits
- ▶ mouthpiece
- ▶ a cap with a clip



Taking Colobreathe using the Turbospin inhaler



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

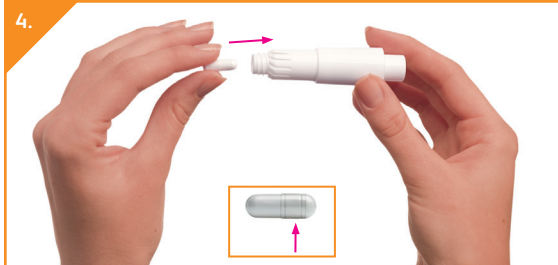


Unscrew the mouthpiece, exposing the chamber of the Turbospin inhaler.

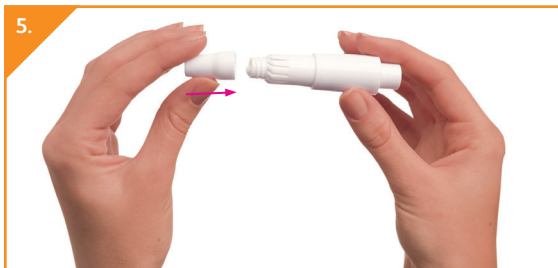


Remove a single capsule from the blister pack. Once you have removed the capsule it must be used immediately.

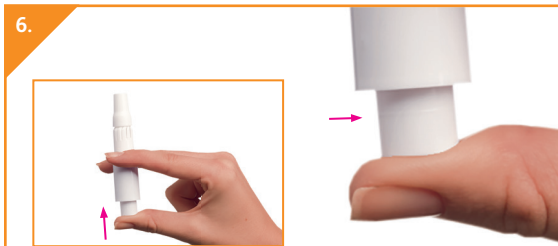
Never try and push the capsule through the foil as this may break the capsule and spill some of the contents.



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



Now replace the mouthpiece by screwing it back into place.



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 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 dose.

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

Then, clean the chamber with a soft tissue or cotton bud.

Never use water.

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

Discard the Turbospin inhaler after you have completed your treatment pack.

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

Side effects

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

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 your mouth out with water after each dose.

Other very common side effects include cough or throat irritation, difficulty in breathing and hoarseness or loss of voice.

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

- ▶ Headache
- ▶ Ringing or buzzing in the ears
- ▶ Problems with balance
- ▶ Coughing up blood, wheezing, chest discomfort, asthma, a productive cough, lung infection
- ▶ Vomiting or nausea
- ▶ Changes in your lung function
- ▶ Joint pains
- ▶ Lack of energy, tiredness
- ▶ Raised temperature

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

For a list of all side effects, please look at the in-pack patient information leaflet or ask your healthcare professional.

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

If you experience any other side effects, you should consult your healthcare professional or pharmacist.

Also, if you experience dizziness, confusion or have problems with your sight, you should avoid driving or using any machines until the symptoms have gone away.

If you are receiving other treatments for cystic fibrosis, you should take them in the following order:

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

However, you should confirm the order of your treatments with your healthcare professional.

If you have any concerns or are unsure about any aspect of your medicine, you should always consult your healthcare professional or pharmacist.

Storing Colobreathe

Once you have taken your dose and cleaned the inhaler, make sure you put the pack away out of the sight and reach of children.

Do not store above 25°C.

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

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

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

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 directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie