

## Package leaflet: Information for the user

**Colobreathe®**

1,662,500 IU inhalation powder, hard capsules

### Colistimethate sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Colobreathe is and what it is used for
2. What you need to know before you use Colobreathe
3. How to use Colobreathe
4. Possible side effects
5. How to store Colobreathe
6. Contents of the pack and other information

### 1. What Colobreathe is and what it is used for

Colobreathe contains colistimethate sodium, a type of antibiotic called a polymyxin.

Colobreathe is used to control persistent lung infections caused by the bacterium *Pseudomonas aeruginosa* in adult patients and children aged 6 years and older with cystic fibrosis.

*Pseudomonas aeruginosa* is a very common bacterium that infects nearly all cystic fibrosis patients at some time during their lives. Some people will get this infection whilst very young but for others it will be much later. If this infection is not properly controlled it will cause damage to the lungs.

### How it works

Colobreathe works by destroying the bacterial cell membrane, having a lethal effect on them.

### 2. What you need to know before you use Colobreathe

#### Do not use Colobreathe:

- if you/your child are allergic to colistimethate sodium, colistin sulphate or polymyxins.

#### Warnings and precautions

Tell your doctor if you/your child has ever had any of the following conditions:

- have reacted badly to inhaled dry powder medicines previously unless this has already been discussed with your doctor.
- already have a muscle condition known as myasthenia gravis or the inherited condition, porphyria
- blood in your sputum (the substance you cough up)

After each inhalation of Colobreathe, the mouth should be rinsed with water. 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.

When you/your child start using Colobreathe, you/your child may find they have 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 a bronchodilator to use before or after taking Colobreathe. If any of these effects become a problem, please contact your doctor who may change your treatment.

If you/your child has any problems with your kidneys or nerves, care should be taken when administering Colobreathe but your doctor should be aware of this.

If you/your child needs to have other forms of colistimethate either by injection or nebulisation caution should be used but your doctor should be aware of this.

#### Children

Do not give Colobreathe to children under the age of 6 years as it is not suitable for them.

#### Other medicines and Colobreathe

Tell your doctor if you/your child are taking, have recently taken or might use any other medicines, and in particular:

- if you/your child are taking aminoglycoside antibiotics used to treat infections caution must be taken;
- if you/your child suffer from myasthenia gravis and are taking macrolide type antibiotics such as azithromycin and clarithromycin, or fluoroquinolones such as norfloxacin and ciprofloxacin. Taking these at the same time as Colobreathe may cause problems with muscle weakness;

- if you/your child are taking colistimethate by injection or nebulisation caution must be taken;
- if you/your child need to have a general anaesthetic caution must be taken.

#### 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 using this medicine.

There is no information about the safety of Colobreathe in pregnant women. Your doctor should advise you before using Colobreathe whether the benefits of the medicine exceed the risks.

Colistimethate sodium may be secreted in the breast milk. Please discuss the use of Colobreathe with your doctor.

#### Driving and using machines

It is possible while using Colobreathe that you may experience dizziness, confusion or have problems with your sight. Do not drive or use any machines until the symptoms have gone away.

### 3. How to use Colobreathe

Always use this medicine exactly as your doctor has told you. Check with your doctor if you/your child are not sure.

The first dose should be given under medical supervision.

#### Dosage

##### Adults and children 6 years of age and older

- The contents of one Colobreathe capsule should be inhaled twice a day using the Turbospin inhaler.
- There should be a 12 hour gap between doses.

#### The order in which other treatments should be taken or carried out

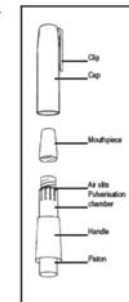
If you/your child are taking other treatments for cystic fibrosis you/your child should take them in the following order:

- Inhaled bronchodilators
- Chest physiotherapy
- Other inhaled medicines
- Then Colobreathe

You/your child should confirm the order of your treatments with your doctor.

### Turbospin inhaler

CE



#### Method of administration

Colobreathe is inhaled into the lungs as a powder from the capsule using the hand-held inhaler called the Turbospin. Colobreathe can only be administered using this device.

#### Do not swallow Colobreathe capsules.

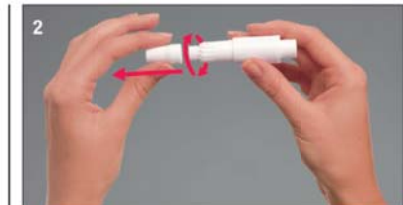
To inhale Colobreathe from the capsule through the Turbospin inhaler follow the procedure described below. Your doctor, pharmacist or nurse should show you/your child how to inhale the medicine when you/your child first start treatment:

#### Taking Colobreathe using the Turbospin inhaler

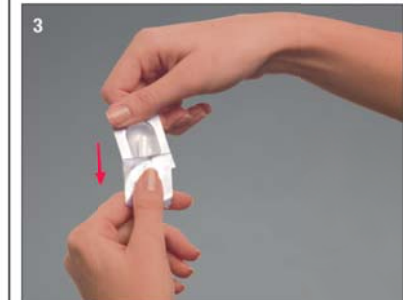
##### Preparing the Turbospin



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



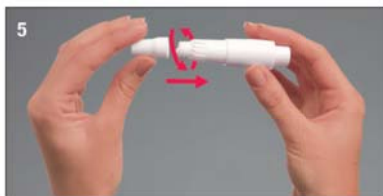
2. Unscrew the mouthpiece, exposing the chamber of the Turbospin inhaler.



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

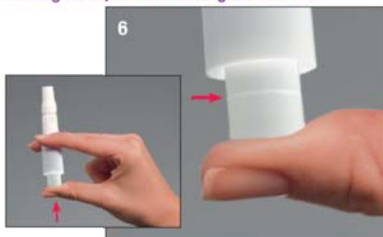


4. Gently insert the capsule into the chamber with the widest end first. No force is required.



5. Now replace the mouthpiece by screwing it back into place.

#### Piercing the capsule and inhaling the medicine



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.



7. 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 sits 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 out.

#### Removing the empty capsule from the Turbospin

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

#### Additional information

As you breathe in slowly, you suck air through the body of the Turbospin inhaler into the capsule chamber. The tiny particles of medication in the capsule are picked up by the airflow and carried 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 device

Clean the Turbospin inhaler after each dose using the following procedure:

1. Deeply press the piston a few times whilst keeping the chamber turned upside down.
2. Clean the chamber using a tissue or cotton bud. Do not use water.

3. Screw the mouthpiece firmly back into place, put the cap back on and the inhaler is ready to be used for your next dose.

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

#### If you/your child forget to use Colobreathe

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 stop using Colobreathe

Do not stop your treatment early unless your doctor says you can. Your doctor will decide how long you/your child's treatment should last.

If you/your child have any further questions on the use of this medicine, ask your doctor.

#### 4. Possible side effects

Like all medicines this medicine can cause side effects, although not everyone gets them.

##### Allergic reactions

An allergic reaction with Colobreathe is possible (typically serious allergic reactions may cause rashes, swelling of the face, tongue and neck, inability to breathe due to narrowing of the airways and loss of consciousness). **If you/your child experience signs of an allergic reaction you should seek urgent medical attention.**

##### Other possible side effects

You/your child may get an unpleasant taste in your mouth after inhaling Colobreathe.

#### Very common: may affect more than 1 in 10 people

- Difficulty in breathing
- Cough, throat irritation
- Hoarse or weak, or even loss of the voice
- Unpleasant taste

#### Common: may affect up to 1 in 10 people

- Headache
- Ringing or buzzing noises in the ear, problems with balance
- Coughing up blood, wheezing, chest discomfort, asthma, productive cough (a cough which brings up mucus), infection of the lungs, lung crackles (your doctor would hear this when listening to your lungs using a stethoscope)
- Vomiting, nausea
- Changes in how your lungs function (found by testing)
- Joint pains
- Lack of energy, tiredness
- Raised temperature

#### Uncommon: may affect up to 1 in 100 people

- Allergic (hypersensitivity) reactions, the signs may include rash and itching
- Weight fluctuations, decreased appetite
- Anxiety
- Fits
- Sleepiness
- Blockage in the ears
- Chest pain
- Shortness of breath
- Nose bleeds, catarrh (mucus in your nose, which may make you feel blocked up), coughing up thick green mucus, pain in the throat and sinuses
- Unusual noises in the chest (your doctor would hear this when listening to your lungs with a stethoscope)
- Diarrhoea, wind
- Excessive production of saliva
- Toothache
- Protein in the urine (found by testing)
- Thirst

The above side effects have been seen in people of all ages with similar frequency.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

##### United Kingdom

Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

##### Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

#### 5. How to store Colobreathe

Keep this medicine out of the sight and reach of children.

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 month.

Do not store Colobreathe above 25°C.

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

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

Discard the Turbospin inhaler after the completion of a treatment pack.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Colobreathe contains

The active substance is colistimethate sodium. Each capsule contains 1,662,500 IU (approximately equivalent to 125 mg) of colistimethate sodium.

The other ingredients are:

**Capsule Shell:**  
Gelatin polyethylene glycol, sodium lauryl sulfate, purified water

##### What Colobreathe looks like and contents of the pack

Colobreathe inhalation powder, hard capsule (inhalation powder) is supplied as small, hard, transparent gelatin capsules containing a fine white powder.

The Turbospin is an inspiratory flow driven dry powder inhaler made of polypropylene and stainless steel.

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

- 56 hard capsules and one Turbospin powder inhaler device sufficient for 4 weeks use.
- 8 hard capsules and one Turbospin inhaler device sufficient for 4 days use.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Teva B.V.  
Swensweg 5, 2031 GA Haarlem, The Netherlands.

#### Manufacturer

Penn Pharmaceutical Services Limited  
Tafarnaubach Industrial Estate  
Tredegar, Gwent, NP22 3AA, United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### United Kingdom

Teva UK Limited  
Tel: +44 1977 628500

#### Ireland

Teva Pharmaceuticals Ireland  
Tel: +353 51 321 740

#### This leaflet was last revised in March 2017

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>

There are also links to other websites about rare diseases and treatments.



AAAJ7515