

## 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.

#### **What is in this leaflet**

1. What Colobreathe is and what it is used for
2. What you need to know before you take 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.

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

##### **Do not use Colobreathe:**

- if you/your child are allergic to colistimethate sodium (sometimes known as colistin), 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)

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 taking this medicine.

There is no information about the safety of Colobreathe in pregnant women. Like all medicines, extra care must be taken during pregnancy. 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**

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.

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.



**Method of administration**

**Do not swallow Colobreathe capsules. They are for use with the Turbospin inhaler only.**

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



1. Remove the cap from the Turbospin inhaler.



2. Unscrew the mouthpiece.



3. Remove a Colobreathe capsule from the protective blister by peeling back the foil. **DO NOT** push the capsule through the foil. **IMPORTANT: Once removed from the foil packaging, use the capsule immediately.**



4. Insert the capsule into the chamber of the Turbospin inhaler.



5. Replace the mouthpiece by screwing back into place.



6. Holding the inhaler with the mouthpiece upwards, push the piston fully in (this pierces the capsule, which will allow the contents to be inhaled) and then release it completely.



7. Breathe out gently then place the mouthpiece between the lips and teeth. Take care not to cover the air slits with your fingers during inhalation.
8. Breathe in through the mouth as deeply as possible.
9. Remove the Turbospin from your mouth and hold your breath for about 10 seconds, or for as long as is comfortable.
10. Repeat steps 7 to 9 two more times or until the capsule is empty. To check if capsule is empty unscrew mouthpiece to see if contents have been inhaled. If not repeat steps 7 to 9 again.
11. Rinse your mouth well with water and then spit the water out after each time you/your child use Colobreathe. **IMPORTANT: DO NOT SWALLOW.**
12. Unscrew mouthpiece.
13. Fully push in the piston in order to remove the empty capsule. Discard the empty capsule.

### **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.

If you/your child get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **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.

Colobreathe capsules should be stored in the primary packaging until immediately before use in order to protect them from moisture.

Do not remove the capsules from the packaging until needed. If you/your child accidentally peel back the foil, and any capsules become exposed, please discard these capsules.

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.

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

The Turbospin inhaler can be recycled according to local requirements.

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

### **What Colobreathe contains**

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

### **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 aluminium 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 and Manufacturer**

### **Marketing Authorisation Holder:**

Forest Laboratories UK Ltd  
Dartford  
Kent  
DA2 6SL  
United Kingdom

### **Manufacturer:**

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

Forest-Tosara Ltd

Unit 146 Baldoyle Ind. Estate, Baldoyle,  
Dublin 13,  
Ireland

**This leaflet was last revised in 11/13**

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.