EMA/808930/2011 corr.
EMEA/H/C/001225

EPAR summary for the public

Colobreathe

colistimethate sodium

This is a summary of the European public assessment report (EPAR) for Colobreathe. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Colobreathe.

What is Colobreathe?

Colobreathe is a medicine that contains the active substance colistimethate sodium. It is available as capsules containing a powder for inhalation using an inhaler device.

What is Colobreathe used for?

Colobreathe is used to manage long-term lung infection caused by the bacteria *Pseudomonas aeruginosa* in patients aged six years and over who have cystic fibrosis.

Cystic fibrosis is an inherited disease that affects the cells in the lungs and the glands in the gut and pancreas which secrete fluids such as mucus and digestive juices. In cystic fibrosis these fluids become thick and viscous, blocking the airways and the flow of digestive juices. The accumulation of mucus in the lungs allows bacteria to grow more easily causing infections, lung damage and breathing problems. Bacterial lung infection with *P. aeruginosa* is frequent in cystic fibrosis patients.

The medicine can only be obtained with a prescription.

How is Colobreathe used?

The contents of Colobreathe capsules are inhaled using a powder inhaler called Turbospin. They are not to be inhaled using any other device.

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The recommended dose is one capsule twice daily, taken as close as possible to 12 hours apart. The very first dose at the start of the treatment should be taken under medical supervision. Treatment may continue for as long as the doctor considers that the patient is benefiting from it.

If the patient is also receiving other treatments for cystic fibrosis, they should be taken in the following order: inhaled bronchodilator, chest physiotherapy, other inhaled medicines and then Colobreathe.

How does Colobreathe work?

The active substance in Colobreathe, colistimethate sodium, is an antibiotic from the polymyxin group. Polymyxins work by disrupting the cell membrane of bacteria by interacting with certain components of the membrane called phospholipids. Polymyxins target a group of bacteria called Gram-negative bacteria, which includes *P. aeruginosa*, because their cell membranes contain a high level of phospholipids.

Colistimethate sodium is a well-known antibiotic that has been used for several years to treat lung infection in cystic fibrosis patients and is available in the form of a solution used with a nebuliser (a machine that changes a solution into an aerosol that the patient can breathe in). Colobreathe, as a powder for inhalation, is expected to be more convenient for patients than nebulisers.

How has Colobreathe been studied?

The effects of Colobreathe were first tested in experimental models before being studied in humans.

Colobreathe was compared with another medicine, tobramycin nebuliser solution, in 380 cystic fibrosis patients aged six years and above with *P. aeruginosa* lung infection. The patients' condition had been stabilised by treatment with tobramycin before the study. The main measure of effectiveness was based on the improvement in FEV1, adjusted for the patients' age and height, after 24 weeks. FEV1 is the most air a person can breathe out in one second.

What benefit has Colobreathe shown during the studies?

Colobreathe compared well with the tobramycin treatment, considering the fact that the patients were already stabilised on tobramycin nebuliser. Among patients that completed the study, the improvement in FEV1 adjusted for age and height was 0.39% with Colobreathe compared with 0.78% with tobramycin. The improvements in FEV1 seen with Colobreathe were considered sufficient proof of effectiveness, considering the fact that the patients in the study were already stabilised on tobramycin nebuliser.

What is the risk associated with Colobreathe?

The most common side effects seen with Colobreathe in studies were: unpleasant taste, cough, throat irritation, difficulty breathing and dysphonia (difficulty speaking). Inhalation may also lead to coughing or bronchospasm (tightening of the muscles in the airway), which may be controlled by first treating the patients with inhaled beta-2 agonist medicines. For the full list of all side effects reported with Colobreathe, see the package leaflet.

Colobreathe must not be used in people who are hypersensitive (allergic) to colistimethate sodium or to colistin sulphate or polymyxin B.

Why has Colobreathe been approved?

The CHMP concluded that the modest improvement in FEV1 seen with Colobreathe was sufficient evidence of the medicine's effectiveness, given that larger improvements would not be expected in patients whose condition was already stabilised on tobramycin nebuliser. In addition, the Committee noted that patients generally prefer inhaling powder to using a nebuliser.

The side effects seen with Colobreathe were considered acceptable. No more serious side effects were seen with Colobreathe than with tobramycin.

The Committee therefore decided that the benefits of Colobreathe are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Colobreathe?

The company that makes Colobreathe will supply education packs to patients and healthcare professionals. The packs will contain information on the need to comply with treatment, instructions on how to use the medicine and information on side effects.

Other information about Colobreathe

The European Commission granted a marketing authorisation valid throughout the European Union for Colobreathe on 13 February 2012.

The full EPAR for Colobreathe can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Colobreathe, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2011.