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EPAR summary for the public

Libertek

roflumilast

This is a summary of the European public assessment report (EPAR) for Libertek. 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 Libertek.

What is Libertek?

Libertek is a medicine that contains the active substance roflumilast. It is available as tablets (500 micrograms).

What is Libertek used for?

Libertek is used to treat severe chronic obstructive pulmonary disease (COPD) in adults who have chronic bronchitis (long-term inflammation of the airways), and whose COPD flares up frequently. COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing air in and out of the lungs.

Libertek is not used on its own but as an 'add-on' to treatment with bronchodilators (medicines that widen the airways in the lungs).

The medicine can only be obtained with a prescription.

How is Libertek used?

The recommended dose of Libertek is one tablet once a day. The tablets should be swallowed with water at the same time each day. Patients may need to take Libertek for several weeks before it starts to have an effect.

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How does Libertek work?

The active substance in Libertek, roflumilast, belongs to a group of medicines called 'phosphodiesterase type 4 (PDE4) inhibitors'. It blocks the action of the PDE4 enzyme, which is involved in the inflammation process that leads to COPD. By blocking the action of PDE4, roflumilast reduces the inflammation in the lungs, helping to reduce the patient's symptoms or to prevent them from getting worse.

How has Libertek been studied?

Libertek has been compared with placebo (a dummy treatment) in two main studies involving over 3,000 adults with severe COPD who had had at least one flare-up of their disease in the past year. The patients could continue to receive treatment with a bronchodilator during the study. The main measure of effectiveness was the improvement in forced expiratory volumes (FEV_1) and the reduction in the number of moderate or severe flare-ups of their COPD over a year of treatment. FEV_1 is the most air a person can breathe out in one second.

What benefit has Libertek shown during the studies?

Libertek was shown to be more effective than placebo at treating COPD. At the beginning of the study, both groups of patients had an FEV_1 of around 1 litre (1,000 ml). After a year, the patients who took Libertek had an average increase of 40 ml while those given placebo had an average decrease of 9 ml. In addition, the patients who took Libertek had an average of 1.1 moderate or severe flare-ups of their disease, compared with 1.4 flare-ups in the patients who took placebo.

What is the risk associated with Libertek?

The most common side effects with Libertek (seen in between 1 and 10 patients in 100) are decreased weight, decreased appetite, insomnia (difficulty sleeping), headache, diarrhoea, nausea (feeling sick) and abdominal pain (stomach ache). Because patients taking Libertek may lose weight, they are advised to weigh themselves on a regular basis. The doctor may stop treatment with Libertek if the patient loses too much weight. For the full list of all side effects reported with Libertek, see the package leaflet.

Libertek must not be used in patients who have moderate or severe problems with their liver. For the full list of restrictions, see the package leaflet.

Why has Libertek been approved?

The CHMP noted that there was a need for new COPD treatments and that the main studies showed a modest benefit of Libertek in patients with severe COPD. This benefit was seen on top of the effects of the treatments that the patients were already receiving. After considering all of the available data on the effects of the medicine, the Committee decided that Libertek's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Libertek?

A risk management plan has been developed to ensure that Libertek is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Libertek, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes Libertek will ensure that healthcare professionals who will prescribe the medicine in all Member States of the European Union (EU) are provided with educational materials containing information on the medicine's side effects and how it should be used. The company will also provide cards for patients, telling them what information that they need to give their doctor about their symptoms and past illnesses to help the doctor know whether Libertek is appropriate for them. The card will include an area where patients can record their weight.

The company is also carrying out an observational study on the long-term safety of the medicine.

Other information about Libertek

The European Commission granted a marketing authorisation valid throughout the European Union for Libertek on 28 February 2011. This authorisation was based on the authorisation granted to Daxas in 2010 ('informed consent').

The full EPAR for Libertek 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 Libertek, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.