



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Refusal of the marketing authorisation for Labazenit (budesonide / salmeterol)

Outcome of re-examination

On 21 March 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Labazenit, intended for the treatment of asthma. The company that applied for authorisation is Laboratoires SMB s.a.

The applicant requested a re-examination of the opinion. After considering the grounds for this request, the CHMP re-examined the initial opinion, and confirmed the refusal of the marketing authorisation on 27 June 2013.

What is Labazenit?

Labazenit is a medicine that contains the active substances budesonide and salmeterol. It was to be available as capsules containing powder for inhalation.

What was Labazenit expected to be used for?

Labazenit was expected to be used in the treatment of asthma in adults for whom a combination product containing an inhaled corticosteroid and long-acting beta-2 agonist is required.

How is Labazenit expected to work?

The two active substances in Labazenit are well known and are present in several medicines used to treat asthma, either alone or in combination with other medicines.

Budesonide is a corticosteroid that works as an anti-inflammatory agent. When inhaled, it reduces inflammation in the airways, thereby helping to keep the patients' airways clear and allowing them to breathe more easily.



Salmeterol is a long-acting beta-2 agonist and it works by attaching to receptors known as beta-2 receptors found in the muscles of the airways. When it attaches to these receptors, it causes the muscles to relax, which keeps the airways open and helps with the patient's breathing.

What did the company present to support its application?

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

The company presented results of two main studies that compared Labazenit with salmeterol alone in a total of 83 asthma patients, and one main study comparing Labazenit with budesonide alone in 375 patients. The primary measures of effectiveness were based on the patients' forced expiratory volumes (FEV₁) or peak expiratory flow (PEF) after treatment. FEV₁ is the maximum volume of air a person can breathe out in one second, while PEF is the maximum speed at which a person can expel air from their lungs.

Two larger supportive studies involving 601 patients were also conducted, comparing Labazenit with other corticosteroid-beta-2 agonist combination treatments.

What were the CHMP's main concerns that led to the refusal?

The CHMP's main concern was that the study comparing Labazenit with budesonide alone did not prove that the anti-inflammatory effect of Labazenit was sufficient. In addition, data from another study indicated that lower amounts of budesonide may reach the lungs when Labazenit is used.

The CHMP therefore concluded that the benefits of the medicine had not been shown to outweigh its risks and recommended that it be refused marketing authorisation.

The CHMP refusal was confirmed after re-examination.

What consequences does this refusal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there were no ongoing clinical trials with Labazenit in Europe at the time of the CHMP's opinion.