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Withdrawal of application to change the marketing authorisation for BiResp Spiromax (budesonide / formoterol)

Teva Pharma B.V. withdrew its application for the use of BiResp Spiromax as a reliever-only treatment in people with mild asthma.

The company withdrew the application on 27 April 2026.

What is BiResp Spiromax and what is it used for?

BiResp Spiromax is a medicine that contains the active substances budesonide and formoterol. It is used to treat asthma in adults and adolescents aged 12 years and above for whom a combination product is considered appropriate. It can be used in patients whose disease is not adequately controlled with other asthma medicines called corticosteroids and 'short-acting beta-2 agonists' taken by inhalation, or in patients whose disease is adequately controlled with corticosteroids and 'long-acting beta-2 agonists' (such as budesonide and formoterol) taken by inhalation.

BiResp Spiromax is also used to relieve the symptoms of severe chronic obstructive pulmonary disease (COPD) in adults who have had exacerbations (flare–ups) of the disease in the past despite regular treatment. COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty in breathing.

BiResp Spiromax has been authorised in the EU since April 2026. It is available as an inhalation powder in a portable inhaler device.

Further information on BiResp Spiromax's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/biresp-spiromax

What change had the company applied for?

Currently BiResp Spiromax is authorised in asthma for maintenance use and as reliever when needed in combination with maintenance treatment. The company applied for an extension of indication so it can also be used for relieving symptoms of mild asthma when needed, with no need for maintenance treatment (reliever-only treatment).

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How does BiResp Spiromax work?

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

Budesonide belongs to a group of anti-inflammatory medicines known as corticosteroids. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system by attaching to receptors in various types of immune cell. This leads to a reduction in the release of substances that are involved in the inflammation process, such as histamine, thereby helping to keep the airways clear and allowing the patient to breathe more easily.

Formoterol is a long-acting beta-2 agonist. 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.

In its use as reliever-only treatment for mild asthma, BiResp Spiromax was expected to work in the same way as it does in its existing uses.

What did the company present to support its application?

The company presented results from published studies and recommendations from international treatment guidelines.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

The Agency noted that the evidence presented did not show sufficiently that budesonide/formoterol was effective when used for reliever-only treatment in people with mild asthma.

There was a concern that the available evidence came from patients that were not fully representative of patients with asthma. There was also a concern that patents on relief-only treatment would not get enough corticosteroid (budesonide) treatment to control their asthma. In addition, the Agency noted issues with the way studies supporting the application were carried out.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of BiResp Spiromax as reliever-only treatment for mild asthma did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it did not have sufficient information to address the issues raised by the Agency.

Does this withdrawal affect patients in clinical trials?

The company informed the CHMP that there were no ongoing clinical trials with BiResp Spiromax in asthma at the time of the withdrawal.

What is happening with BiResp Spiromax for the treatment of other diseases?

BiResp Spiromax continues to be authorised in authorised uses.