



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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BiResp Spiromax (*budesonide / formoterol*)

An overview of BiResp Spiromax and why it is authorised in the EU

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 is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substances, but BiResp Spiromax is given using a different inhaler. The reference medicine for BiResp Spiromax is Symbicort Turbohaler.

How is BiResp Spiromax used?

The medicine can only be obtained with a prescription. It is available as an inhalation powder in a portable inhaler device, and each inhalation provides a fixed dose of the medicine. BiResp Spiromax 160/4.5 micrograms (160 micrograms of budesonide and 4.5 micrograms of formoterol) can be used for the regular treatment of asthma and when needed as a reliever. It can also be used for the treatment of COPD symptoms in adult patients. The higher strength, BiResp Spiromax 320/9 microgram (320 micrograms of budesonide and 9 micrograms of formoterol), can only be used for the regular treatment of asthma and for the treatment of COPD symptoms.

For the regular treatment of asthma, the recommended dose is 1 to 4 inhalations twice a day, depending on the strength being used, age and the severity of the asthma. As asthma reliever therapy, patients can take 1 or 2 additional inhalations of BiResp Spiromax 160/4.5 microgram only to relieve their symptoms. If patients need to take more than 8 inhalations per day, it is recommended they speak to their doctor to have their asthma therapy reconsidered.

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For the treatment of COPD, the recommended dose is 1 or 2 inhalations twice a day, depending on the strength being used.

For further information, see the package leaflet or contact your doctor or pharmacist.

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.

How has BiResp Spiromax been studied?

Studies on the benefits and risks of the active substances in the authorised uses have already been carried out with the reference medicine, Symbicort Turbohaler, and do not need to be repeated for BiResp Spiromax.

As for every medicine, the company provided studies on the quality of BiResp Spiromax. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of BiResp Spiromax?

Because BiResp Spiromax is a hybrid medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is BiResp Spiromax authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, BiResp Spiromax 160/4.5 micrograms and 320/9 micrograms have been shown to have comparable quality and to be bioequivalent to the corresponding strengths of Symbicort Turbohaler. Therefore, the Agency's view was that, as for Symbicort Turbohaler, the benefit outweighs the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of BiResp Spiromax have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of BiResp Spiromax are continuously monitored. Suspected side effects reported with the medicine are carefully evaluated and any necessary action taken to protect patients.

Other information about BiResp Spiromax

BiResp Spiromax received a marketing authorisation valid throughout the EU on 28 April 2014.

Further information on BiResp Spiromax can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/biresp-spiromax..

This overview was last updated in 05-2021.