



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/121020/2014  
EMA/H/C/002348

## EPAR summary for the public

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# DuoResp Spiromax

budesonide / formoterol

This is a summary of the European public assessment report (EPAR) for DuoResp Spiromax. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use DuoResp Spiromax.

For practical information about using DuoResp Spiromax, patients should read the package leaflet or contact their doctor or pharmacist.

## What is DuoResp Spiromax and what is it used for?

DuoResp Spiromax is a medicine that contains the active substances budesonide and formoterol. It is used for the treatment of asthma in adults for whom a combination product is considered appropriate. It can be used in patients whose disease is not adequately controlled by treatment with other asthma medicines called corticosteroids and 'short-acting beta-2 agonists' taken by inhalation, or in patients whose disease is adequately controlled by treatment with corticosteroids and 'long-acting beta-2 agonists' taken by inhalation.

DuoResp 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.

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

## How is DuoResp 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. DuoResp Spiromax



160/4.5 microgram (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. The higher strength, DuoResp 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.

For the regular treatment of asthma, the recommended dose is 1 to 4 inhalations twice a day, depending on the strength being used and the severity of the asthma. As asthma reliever therapy, patients can take 1 or 2 additional inhalations of DuoResp 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.

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.

### **How does DuoResp Spiromax work?**

The two active substances in DuoResp 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 DuoResp Spiromax been studied?**

Studies in patients have been limited to tests to determine that DuoResp Spiromax is bioequivalent to the reference medicine, Symbicort Turbohaler. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

### **What are the benefits and risks of DuoResp Spiromax?**

Because DuoResp 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 DuoResp Spiromax approved?**

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that DuoResp Spiromax 160/4.5 microgram and 320/9 microgram have been shown to have comparable quality and to be bioequivalent to the corresponding strengths of Symbicort Turbohaler. Therefore, the CHMP's view was that, as for Symbicort Turbohaler, the benefit outweighs the identified risk. The Committee recommended that DuoResp Spiromax be given marketing authorisation.

The company initially also applied for a lower strength of DuoResp Spiromax, however bioequivalence to the reference product was not demonstrated and the application for this strength was withdrawn.

## **What measures are being taken to ensure the safe and effective use of DuoResp Spiromax?**

A risk management plan has been developed to ensure that DuoResp Spiromax 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 DuoResp Spiromax, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

## **Other information about DuoResp Spiromax**

The European Commission granted a marketing authorisation valid throughout the European Union for DuoResp Spiromax on 28 April 2014.

The full EPAR and risk management plan summary for DuoResp Spiromax can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with DuoResp Spiromax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2014.