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EPAR summary for the public

Airexar Spiromax

salmeterol / fluticasone propionate

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

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

What is Airexar Spiromax and what is it used for?

Airexar Spiromax is a medicine used for the regular treatment of adults with severe asthma and for the relief of symptoms of chronic obstructive pulmonary disease (COPD, a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty in breathing). It contains the active substances salmeterol (a so-called long-acting beta-2 agonist) and fluticasone propionate (a corticosteroid).

In asthma, Airexar Spiromax can be used in patients whose disease is not adequately controlled despite treatment with a combination of a beta-2 agonist and a lower dose of inhaled corticosteroid, or those whose asthma is already controlled with a long-acting beta-2 agonist and a high-dose of inhaled corticosteroid.

In COPD, Airexar Spiromax is used in adults who have had exacerbations (flare–ups) of the disease in the past and have significant symptoms despite regular treatment.

Airexar Spiromax is a 'hybrid medicine'. This means that Airexar Spiromax is similar to a 'reference medicine' called Seretide Diskus (also known as Seretide Accuhaler), which contains the same active substances. However, Airexar Spiromax is available only as a single high strength, whereas the reference medicine is available in three strengths, the same high strength and two lower strengths. As Airexar Spiromax is only available in one high strength, its use in asthma has been restricted to patients whose disease is severe.

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How is Airexar Spiromax used?

Airexar Spiromax is available as an inhalation powder in a portable inhaler device. Each inhalation provides a fixed dose of the medicine.

The recommended dose is one inhalation twice a day. Patients should be regularly assessed by a doctor to ensure that they receive the lowest dose sufficient to control symptoms. Since Airexar Spiromax is only available in one high strength (containing 50 micrograms of salmeterol and 500 micrograms of fluticasone propionate), should a lower strength become appropriate, patients should be switched to an alternative combination of salmeterol and fluticasone propionate containing a lower dose of fluticasone propionate.

Airexar Spiromax can only be obtained with a prescription. For further information, see the package leaflet.

How does Airexar Spiromax work?

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

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

Fluticasone propionate 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.

How has Airexar Spiromax been studied?

Studies in people have been limited to tests to determine that Airexar Spiromax is bioequivalent to the reference medicine, Seretide Diskus. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Airexar Spiromax?

Because Airexar 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 Airexar Spiromax approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Airexar Spiromax has been shown to have comparable quality and to be bioequivalent to Seretide Diskus. Therefore, the CHMP's view was that, as for Seretide Diskus, the benefit outweighs the identified risk. The Committee recommended that Airexar Spiromax be approved for use in the EU.

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

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

Other information about Airexar Spiromax

The European Commission granted a marketing authorisation valid throughout the European Union for Airexar Spiromax on 18 August 2016.

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

This summary was last updated in 08-2016.