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Seffalair Spiromax (*salmeterol / fluticasone*)

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

What is Seffalair Spiromax and what is it used for?

Seffalair Spiromax is a medicine used for the regular treatment of asthma in adults and adolescents above 12 years of age. It is used in patients whose disease is not adequately controlled despite treatment with a combination of a short-acting beta-2 agonist and inhaled corticosteroid. It contains the active substances salmeterol and fluticasone.

How is Seffalair Spiromax used?

The medicine can only be obtained with a prescription. It is available as an inhalation powder in an inhaler device.

It comes in two strengths, one containing 12.75 micrograms of salmeterol and 100 micrograms of fluticasone and a higher strength (containing 12.75 micrograms of salmeterol and 202 micrograms of fluticasone).

Patients use one inhalation twice a day (one in the morning and one in the evening); the doctor will decide which strength is appropriate (and change it when necessary) based on how severe the asthma is and how well it has been controlled. Once the asthma is controlled doctors should consider changing patients to inhaled corticosteroid alone.

Patients should be shown how to use the inhaler correctly by a doctor or other healthcare professional.

The delivered doses for Seffalair Spiromax are different from other salmeterol / fluticasone containing products. Seffalair Spiromax should therefore not be swapped with other salmeterol / fluticasone containing inhalers.

For more information about using Seffalair Spiromax, see the package leaflet or contact your doctor or pharmacist.

How does Seffalair Spiromax work?

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Salmeterol is a long-acting beta-2 agonist. It attaches to beta-2 receptors in the muscles of the airways and causes the muscles of the airways to relax and widen, allowing the patient to breathe more easily.

Fluticasone is a corticosteroid. It reduces the activity of the immune system by attaching to receptors in various types of immune cells, blocking the release of substances involved in the inflammation process. This reduces inflammation in the airways and improves the patient's breathing.

What benefits of Seffalair Spiromax have been shown in studies?

Two main studies in 1,375 patients with asthma have shown that Seffalair Spiromax is effective at improving patients' FEV_1 (the maximum volume of air they can breathe out in one second).

In the first study, patients treated with Seffalair Spiromax (containing 12.75 micrograms of salmeterol and 100 micrograms of fluticasone) for 12 weeks had FEV_1 increases of 315 ml, compared with 204 ml for patients treated with a comparable dose of inhaled fluticasone, and 53 ml for patients treated with placebo.

In the second study, patients treated with Seffalair Spiromax (containing 12.75 micrograms of salmeterol and 100 micrograms of fluticasone) had FEV_1 increases of 271 ml, compared with 119 ml for patients treated with a comparable dose of inhaled fluticasone, and a decrease of 4 ml for patients treated with placebo. For the higher strength Seffalair Spiromax FEV_1 increases were 272 ml, compared with 179 ml for patients treated with a comparable dose of inhaled fluticasone.

What are the risks associated with Seffalair Spiromax?

The most common side effects with Seffalair Spiromax (which may affect up to 1 in 10 people) are nasopharyngitis (inflammation of the nose and throat), headache, cough and oral candidiasis (thrush, a fungal infection).

For the full list of side effects and restrictions of Seffalair Spiromax, see the package leaflet.

Why is Seffalair Spiromax authorised in the EU?

Seffalair Spiromax improves breathing in patients with asthma. It contains two active substances which are well known and already marketed as combination inhalers. The safety profile of Seffalair Spiromax is considered similar to that of other similar inhaler medicines. The European Medicines Agency decided that Seffalair Spiromax's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Seffalair Spiromax

Seffalair Spiromax received a marketing authorisation valid throughout the EU on 26 March 2021.

Further information on Seffalair Spiromax can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/seffalair-spiromax

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