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EPAR summary for the public

Vylaer Spiromax

budesonide / formoterol

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

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

What is Vylaer Spiromax and what is it used for?

Vylaer 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.

Vylaer 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.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How is Vylaer 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. Vylaer Spiromax 160/4.5 microgram can be used for the regular treatment of asthma. It can also be used 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. For asthma reliever therapy, patients should take a separate 'reliever inhaler' to relieve their symptoms. If patients need to take more than 8 reliever 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 Vylaer Spiromax work?

The two active substances in Vylaer 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 inhaled it mainly attaches to the receptors in the airways and causes the muscles to relax, which keeps the airways open and helps with the patient's breathing.

What are the benefits and risks of Vylaer Spiromax?

Studies were carried out to show that Vylaer Spiromax is bioequivalent to the reference medicine (i.e. produces the same level of the active substance in the body) and that the two medicines act in the same way. The benefits and risks of Vylaer Spiromax are therefore taken to be the same as those of the reference medicine.

Why is Vylaer Spiromax approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Vylaer Spiromax 160/4.5 microgram and 320/9 microgram have been shown to have comparable quality and to be equivalent 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 Vylaer Spiromax be given marketing authorisation.

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

A risk management plan has been developed to ensure that Vylaer 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 Vylaer 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 Vylaer Spiromax

The European Commission granted a marketing authorisation valid throughout the European Union for Vylaer Spiromax on 19 November 2014.

The full EPAR and risk management plan summary for Vylaer 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 Vylaer Spiromax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2014.