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Bevespi Aerosphere (*glycopyrronium bromide / formoterol*)

An overview of Bevespi Aerosphere and why it is authorised in the EU

What is Bevespi Aerosphere and what is it used for?

Bevespi Aerosphere is a medicine used in adults to relieve the symptoms of chronic obstructive pulmonary disease (COPD). COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing.

Bevespi Aerosphere is used for maintenance (regular) treatment. It contains the active substances glycopyrronium bromide and formoterol.

How is Bevespi Aerosphere used?

Bevespi Aerosphere is available as a liquid in a portable inhaler device. The recommended dose is 2 inhalations twice a day.

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

The medicine can only be obtained with a prescription. For more information about using Bevespi Aerosphere, see the package leaflet or contact your doctor or pharmacist.

How does Bevespi Aerosphere work?

The two active substances in Bevespi Aerosphere work in different ways to widen the airways and improve breathing in COPD.

Glycopyrronium bromide is a muscarinic receptor antagonist. This means that it blocks muscarinic receptors (targets) in muscle cells in the lungs. Because these receptors help control the contraction of muscles, when glycopyrronium is inhaled, it causes the muscles of the airways to relax, helping to keep the airways open.

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.

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What benefits of Bevespi Aerosphere have been shown in studies?

Three main studies in over 5,000 patients with COPD have shown that Bevespi Aerosphere is effective at improving patients' FEV_1 (the maximum volume of air they can breathe out in one second).

In these studies, patients treated with Bevespi Aerosphere for 24 weeks had FEV_1 increases of around 135 to 150 ml. Patients who received placebo (a dummy treatment), on the other hand, had increases of up to 8 ml or reductions of up to 20 ml.

The studies also showed that Bevespi Aerosphere improved FEV_1 more than the single components in the medicine.

Finally, the studies showed that Bevespi Aerosphere can lead to modest improvements in symptoms such as breathlessness.

What are the risks associated with Bevespi Aerosphere?

The most common side effects with Bevespi Aerosphere (which may affect up to 1 in 10 people) include headache, nausea (feeling sick), muscle spasms and dizziness.

For the full list of side effects and restrictions of Bevespi Aerosphere, see the package leaflet.

Why is Bevespi Aerosphere authorised in the EU?

The components in Bevespi Aerosphere are well established treatments of COPD. The combination has been shown to be effective at improving patients' lung function, with both components contributing to this effect. The medicine has also shown some effect on symptoms such as breathlessness although this appears modest.

Side effects are considered mild to moderate in severity and are similar to other COPD medicines.

The European Medicines Agency therefore decided that Bevespi Aerosphere'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 Bevespi Aerosphere?

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

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

Other information about Bevespi Aerosphere

Bevespi Aerosphere received a marketing authorisation valid throughout the EU on 18 December 2018.

Further information on Bevespi Aerosphere can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Bevespi-Aerosphere.

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