



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Trixeo Aerosphere (*formoterol / glycopyrronium bromide / budesonide*)

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

What is Trixeo Aerosphere and what is it used for?

Trixeo Aerosphere is a medicine used to treat patients with moderate to severe chronic obstructive pulmonary disease (COPD), a long-term disease in which the airways and air sacs in the lungs become damaged or blocked, leading to difficulty breathing.

Trixeo Aerosphere is used for maintenance (regular) treatment in adults whose disease is not controlled well enough with a combination of inhaled medicines consisting of a long-acting beta-2 agonist plus either a corticosteroid or a long-acting muscarinic antagonist.

Trixeo Aerosphere contains the active substances formoterol, glycopyrronium bromide and budesonide.

How is Trixeo Aerosphere used?

Trixeo Aerosphere can only be obtained with a prescription. It is available in a portable inhaler device. The recommended dose is two inhalations twice a day (two in the morning and two in the evening). Patients should be shown how to use the inhaler correctly by a doctor or other healthcare professional.

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

How does Trixeo Aerosphere work?

Trixeo Aerosphere contains three active substances, which work in different ways to widen the airways and improve breathing in COPD.

Formoterol is a long-acting beta-2 agonist. It attaches to receptors (targets) known as beta-2 receptors 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.

Glycopyrronium bromide is a long-acting muscarinic receptor antagonist. This means that it blocks muscarinic receptors in muscle cells in the airways. Because these receptors help control the contraction of muscles, glycopyrronium causes the muscles of the airways to relax, helping to keep the airways open.



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 (the body's natural defences) 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 keeping the airways clear and allowing the patient to breathe more easily.

What benefits of Trixeo Aerosphere have been shown in studies?

Two main studies in over 10,000 patients with moderate to very severe COPD have shown that Trixeo Aerosphere is effective at improving patients' FEV₁ (the maximum volume of air they can breathe out in one second) and at reducing the number of exacerbations (flare-ups) of the disease.

In the first study, patients treated with Trixeo Aerosphere for 24 weeks had FEV₁ increases of around 147 ml, compared with 125 ml for patients treated with glycopyrronium/formoterol, and 73 ml and 88 ml for patients treated with two different inhalers containing budesonide/formoterol.

The second study, which lasted one year, showed that patients treated with Trixeo Aerosphere had fewer COPD exacerbations (1.08 per year) than patients treated with with glycopyrronium/formoterol (1.42) or budesonide/formoterol (1.24).

What are the risks associated with Trixeo Aerosphere?

The most common side effects with Trixeo Aerosphere (which may affect up to 1 in 10 people) are pneumonia (lung infection), headache and urinary tract infection.

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

Why is Trixeo Aerosphere authorised in the EU?

Trixeo Aerosphere improved lung function in patients with moderate to severe COPD, and reduced disease exacerbations. The safety profile of Trixeo Aerosphere is considered similar to that of medicines containing combinations of a corticosteroid, beta-2 agonist and antimuscarinic. The European Medicines Agency therefore decided that Trixeo 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 Trixeo Aerosphere?

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

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

Other information about Trixeo Aerosphere

Trixeo Aerosphere received a marketing authorisation valid throughout the EU on 09 December 2020.

Further information on Trixeo Aerosphere can be found on the Agency's website:

www.ema.europa.eu/medicines/human/EPAR/trixeo-aerosphere.

This overview was last updated in 12-2020.