EMA/118969/2020
EMEA/H/C/004882

Budesonide/Formoterol Teva Pharma B.V. (*budesonide/formoterol*)

An overview of Budesonide/Formoterol Teva Pharma B.V. and why it is authorised in the EU

What is Budesonide/Formoterol Teva Pharma B.V. and what is it used for?

Budesonide/Formoterol Teva Pharma B.V. is a medicine 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;
- whose disease is adequately controlled by treatment with corticosteroids and 'long-acting beta-2 agonists' taken by inhalation.

Budesonide/Formoterol Teva Pharma B.V. 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.

Budesonide/Formoterol Teva Pharma B.V. is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substances, but Budesonide/Formoterol Teva Pharma B.V. is given using a different inhaler. The reference medicine for Budesonide/Formoterol Teva Pharma B.V. is Symbicort Turbohaler.

Budesonide/Formoterol Teva Pharma B.V. contains the active substances budesonide and formoterol.

How is Budesonide/Formoterol Teva Pharma B.V. used?

The medicine is available as an inhalation powder in a portable inhaler device, and each inhalation provides a fixed dose of the medicine.

Budesonide/Formoterol Teva Pharma B.V. is available in 2 strengths:

- 160/4.5 microgram (160 micrograms of budesonide and 4.5 micrograms of formoterol), which can be used both for the regular treatment of asthma and when needed as a reliever. It can also be used for the treatment of COPD;

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- 320/9 microgram (320 micrograms of budesonide and 9 micrograms of formoterol) can only be used for the regular treatment of asthma and 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 asthma.

As *asthma reliever therapy*, patients can take 1 or 2 additional inhalations of Budesonide/Formoterol Teva Pharma B.V. 160/4.5 microgram only to relieve their symptoms. If patients need to take more than 8 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.

The medicine can only be obtained with a prescription. For more information about using Budesonide/Formoterol Teva Pharma B.V., see the package leaflet or contact your doctor or pharmacist.

How does Budesonide/Formoterol Teva Pharma B.V. work?

The two active substances in Budesonide/Formoterol Teva Pharma B.V. 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 keeping the airways clear and allowing the patient to breathe more easily.

Formoterol is a long-acting beta-2 agonist. It attaches 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 and helps with the patient's breathing.

How has Budesonide/Formoterol Teva Pharma B.V. been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Symbicort Turbohaler, and do not need to be repeated for Budesonide/Formoterol Teva Pharma B.V.

As for every medicine, the company provided studies on the quality of Budesonide/Formoterol Teva Pharma B.V. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Budesonide/Formoterol Teva Pharma B.V.?

Because Budesonide/Formoterol Teva Pharma B.V. 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 Budesonide/Formoterol Teva Pharma B.V. authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Budesonide/Formoterol Teva Pharma B.V. has been shown to have comparable quality and to be bioequivalent to the corresponding strengths of Symbicort Turbohaler. Therefore, the Agency's view was that as for Symbicort Turbohaler, the benefits of Budesonide/Formoterol Teva Pharma B.V. outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Budesonide/Formoterol Teva Pharma B.V.?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Budesonide/Formoterol Teva Pharma B.V. have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Budesonide/Formoterol Teva Pharma B.V. are continuously monitored. Side effects reported with Budesonide/Formoterol Teva Pharma B.V. are carefully evaluated and any necessary action taken to protect patients.

Other information about Budesonide/Formoterol Teva Pharma B.V.

Budesonide/Formoterol Teva Pharma B.V. received a marketing authorisation valid throughout the EU on 3 April 2020.

Further information on Budesonide/Formoterol Teva Pharma B.V. can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/budesonide-formoterol-teva-pharma-bv.

This overview was last updated in 03-2020.