

Summary Public Assessment Report

Fortibec

**(beclometasone dipropionate (anhydrous),
formoterol fumarate dihydrate)**

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Pressurised inhalation, solution, 100 microgram/6 microgram/dose, 200 microgram/6 microgram/dose

This is a summary of the public assessment report (PAR) for Fortibec. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fortibec and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Innovair.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

100 microgram/6 microgram/dose

Asthma

The product is indicated in the regular treatment of asthma in adult patients in whom:

- the asthma is not adequately controlled by using inhaled corticosteroids and "as needed" short-acting bronchodilators or
- the asthma is responding well to treatment with both corticosteroids and long-acting bronchodilators.

COPD

The product can also be used to treat the symptoms of severe chronic obstructive pulmonary disease (COPD) in adult patients. COPD is a long-term disease of the airways in the lungs which is primarily caused by cigarette smoking.

200 microgram/6 microgram/dose

Asthma

The product is used to treat asthma in adults when either:

- the asthma is not adequately controlled by using inhaled corticosteroids and "as needed" short-acting bronchodilators or
- the asthma is responding well to treatment with both corticosteroids and long-acting bronchodilators.

How does Fortibec work?

The two active substances are beclometasone dipropionate and formoterol fumarate dihydrate.

Beclometasone dipropionate belongs to a group of medicines called corticosteroids which have an anti-inflammatory action reducing the swelling and irritation in your lungs.

Formoterol fumarate dihydrate belongs to a group of medicines called long-acting bronchodilators which relax the muscles in your airways and helps you to breathe more easily.

How is Fortibec used?

The pharmaceutical form is a pressurised inhalation solution for inhalation.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Fortibec have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Innovair, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Fortibec?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Fortibec approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Innovair, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product 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, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Fortibec

The full PAR for Fortibec can be found on the following website: [MRI - Home](#). For more information about treatment with Fortibec, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09.