LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

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

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Summary Public Assessment Report

Befoair
beclometasone dipropionate (anhydrous), formoterol fumarate dihydrate

pressurised inhalation, solution, 100/6 micrograms/actuation, 200/6 micrograms/actuation

This is a summary of the public assessment report (PAR) for Befoair. 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 Befoair 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 substances.

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.

100/6 micrograms/actuation

The product provides relief from symptoms such as shortness of breath, wheezing and cough in patients with asthma or COPD and also helps to prevent these symptoms.

Asthma
Befoair is indicated for the regular treatment of asthma in adult patients in whom:
- asthma is not adequately controlled with inhaled corticosteroids and as-needed short-acting bronchodilators

or
- asthma is responding well to treatment with corticosteroids and long-acting bronchodilators.

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

200/6 micrograms/actuation

The product helps to prevent asthma symptoms such as shortness of breath, wheezing and coughing. Befoair 200/6 should not be used in children and adolescent younger than 18 years.

Asthma
Befoair is indicated for the regular treatment of asthma in adult patients in whom:
- asthma is not adequately controlled with inhaled corticosteroids and as-needed short-acting bronchodilators

or
- asthma is responding well to treatment with corticosteroids and long-acting bronchodilators.

How does Befoair work?

Befoair is a pressurised inhalation solution containing two active substances which are inhaled through your mouth and delivered directly into your lungs.

The two active substances are:
Beclometasone dipropionate, which belongs to a group of medicines called corticosteroids that have an anti-inflammatory action reducing the swelling and irritation in your lungs.

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

How is Befoair used?

The pharmaceutical form is pressurised inhalation, solution for oral use.

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 Befoair 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 Befoair?

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 Befoair approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be 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 Befoair?

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 Befoair

The full PAR for Befoair can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Befoair, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-07.