LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Airbufo Forspiro
(budesonide, formoterol fumarate dehydrate)

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(budesonide, formoterol fumarate dihydrate)

Inhalation powder, 160 µg/dose (budesonide), 4,5 µg/dose (formoterol fumarate dehydrate)

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

For practical information about using Airbufo Forspiro, patients should read the package leaflet or contact their doctor or pharmacist.

What is Airbufo Forspiro and what is it used for?

Airbufo Forspiro is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substances. The company has provided additional own data to demonstrate therapeutic equivalence between Airbufo Forspiro and the reference medicine. The reference medicine for Airbufo Forspiro is Symbicort Turbuhaler.

Airbufo Forspiro is an inhaler that is used to treat:

- **asthma in adults and adolescents aged 12-17 years**.
- symptoms of **Chronic Obstructive Pulmonary Disease (COPD) in adults** aged 18 years and older.

How does Airbufo Forspiro work?

This medicinal product contains formoterol and budesonide, which have different modes of action and show additive effects in terms of reduction of asthma exacerbations. The specific properties of budesonide and formoterol allow the combination to be used either as maintenance and reliever therapy or as maintenance treatment of asthma.

Budesonide
Budesonide is a glucocorticosteroid which when inhaled has a dose-dependent anti-inflammatory action in the airways, resulting in reduced symptoms and fewer asthma exacerbations. Inhaled budesonide has less severe adverse reactions than systemic corticosteroids. The exact mechanism responsible for the anti-inflammatory effect of glucocorticosteroids is unknown.

Formoterol
Formoterol is a selective β2 adrenoceptor agonist that, when inhaled, results in rapid and long-acting relaxation of bronchial smooth muscle in patients with reversible airways

obstruction. The bronchodilating effect is dose dependent, with an onset of effect within 1-3 minutes. The duration of effect is at least 12 hours after a single dose.

How is Airbufo Forspiro used?

The pharmaceutical form of Airbufo Forspiro is inhalation powder 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.

What benefits of Airbufo Forspiro have been shown in studies?

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

What are the possible side effects of Airbufo Forspiro?

For the full list of all side effects reported with Airbufo Forspiro, see section 4 of the package leaflet.

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

Why is Airbufo Forspiro approved?

This medicine is similar to a reference medicine containing the same active substances. The company has provided own data to demonstrate therapeutic equivalence between Airbufo Forspiro and the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Airbufo Forspiro benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Airbufo Forspiro 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 for Airbufo Forspiro, 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 Airbufo Forspiro

The marketing authorisation for Airbufo Forspiro was granted on 2018-05-24 in Sweden.

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

This summary was last updated in 2018-08.