LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bufoler Easyhaler
(budesonide, formoterol)

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Summary Public Assessment Report

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(budesonide, formoterol)

Inhalation powder
160 micrograms/4.5 micrograms
320 micrograms/9 micrograms per inhalation

This is a summary of the public assessment report (PAR) for Bufoler Easyhaler. It explains how Bufoler Easyhaler 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 Bufoler Easyhaler.

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

What is Bufoler Easyhaler and what is it used for?

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

The company has provided own data to demonstrate therapeutic equivalence between Bufoler Easyhaler and the reference medicine. The reference medicine for Bufoler Easyhaler is Symbicort Turbuhaler.

Bufoler Easyhaler is an inhaler that is used to treat asthma in adults and adolescents aged 12 years and older. It is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older.

How does Bufoler Easyhaler work?

Bufoler Easyhaler contains two different medicines: budesonide and formoterol.

Budesonide belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.

Formoterol belongs to a group of medicines called 'long-acting $beta_2$adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

How is Bufoler Easyhaler used?

The pharmaceutical form of Bufoler Easyhaler is inhalation powder.

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 Bufoler Easyhaler have been shown in studies?

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

What are the possible side effects of Bufoler Easyhaler?

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

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

Why is Bufoler Easyhaler approved?

This medicine is similar to a reference medicine containing the same active substance. The company has provided own data to demonstrate therapeutic equivalence between Bufoler Easyhaler and the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Bufoler Easyhaler's 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 Bufoler Easyhaler?

A risk management plan has been developed to ensure that Bufoler Easyhaler 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 Bufoler Easyhaler, 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 Bufoler Easyhaler

The marketing authorisation for Bufoler Easyhaler was granted on 2016-01-22 in Sweden.

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

This summary was last updated in 2025-01.