LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bufori Easyhaler
(budesonide, formoterol fumarate dihydrate)

SE/H/1595/01-03/DC

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

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

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

What is Bufori Easyhaler and what is it used for?

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

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

80 micrograms/4.5 micrograms/inhalation
Bufori Easyhaler is an inhaler that is used to treat asthma in adults, adolescents and children aged 6 years and older. This medicine is not suitable for people with severe asthma.

160 micrograms/4.5 micrograms/inhalation and 320 micrograms/9 micrograms/inhalation
Bufori 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 Bufori Easyhaler work?

Bufori Easyhaler contains two different medicines: budesonide and formoterol fumarate dihydrate.

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

Formoterol fumarate dihydrate 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 Bufori Easyhaler used?

The pharmaceutical form of Bufori 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 Bufori Easyhaler have been shown in studies?

Because Bufori 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 Bufori Easyhaler?

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

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

Why is Bufori Easyhaler 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 Bufori Easyhaler and the reference medicine.

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

A risk management plan has been developed to ensure that Bufori 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 Bufori 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 Bufori Easyhaler

The marketing authorisation for Bufori Easyhaler was granted on 2016-11-02 in Sweden.

The full PAR for Bufori Easyhaler can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Bufori Easyhaler, please read the [package leaflet - 80/4.5], [package leaflet - 160/4.5], [package leaflet - 320/9] or contact your doctor or pharmacist.

This summary was last updated in 2025-01.