LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bufomix Easyhaler
(budesonide, formoterol)

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Summary Public Assessment Report

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(budesonide, formoterol)

Inhalation powder
80 micrograms/4.5 micrograms

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

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

What is Bufomix Easyhaler and what is it used for?

Bufomix 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 Bufomix Easyhaler and the reference medicine. The reference medicine for Bufomix Easyhaler is Symbicort Turbuhaler.

Bufomix 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.

How does Bufomix Easyhaler work?

Bufomix 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 Bufomix Easyhaler used?

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

Because Bufomix 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 Bufomix Easyhaler?

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

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

Why is Bufomix 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 Bufomix Easyhaler and the reference medicine.

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

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

The marketing authorisation for Bufomix Easyhaler was granted on 2016-03-31 in Sweden.

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

This summary was last updated in 2016-03.