

Summary Public Assessment Report

Bufomide Easyhaler (budesonide, formoterol fumarate dihydrate)

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(budesonide, formoterol fumarate dihydrate)

Inhalation powder

80 micrograms/4.5 micrograms per inhalation

160 micrograms/4.5 micrograms per inhalation

320 micrograms/9 micrograms per inhalation

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

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

What is Bufomide Easyhaler and what is it used for?

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

80 micrograms/4.5 micrograms/inhalation

Bufomide 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

Bufomide Easyhaler is an inhaler that is used to treat asthma in adults and adolescents aged 12 - 17 years. It is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older.

How does Bufomide Easyhaler work?

Bufomide 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 beta2adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

How is Bufomide Easyhaler used?

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

Because Bufomide Easyhaler is a hybrid application and is considered to be therapeutic equivalent to the reference medicine 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 Bufomide Easyhaler?

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

Why is Bufomide 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 Bufomide Easyhaler and the reference medicine.

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

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

The marketing authorisation for Bufomide Easyhaler was granted on 2017-01-13 in Sweden.

The full PAR for Bufomide Easyhaler can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Bufomide 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 2017-02.