

Summary Public Assessment Report

Fobumix 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 Fobumix Easyhaler. It explains how Fobumix 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 Fobumix Easyhaler.

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

What is Fobumix Easyhaler and what is it used for?

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

80 micrograms/4.5 micrograms/inhalation

Fobumix Easyhaler is an inhaler that is used to treat asthma in adults aged 18 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

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

Fobumix Easyhaler is indicated for use in adults 18 years of age and older only.

Fobumix Easyhaler is NOT indicated for use in children 12 years of age and younger or adolescents 13 to 17 years of age.

How does Fobumix Easyhaler work?

Fobumix 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 Fobumix Easyhaler used?

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

Because Fobumix 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 Fobumix Easyhaler?

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

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

Why is Fobumix 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 Fobumix Easyhaler and the reference medicine.

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

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

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

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