LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Symbicort
(budesonide, formoterol, formoterol fumarate dihydrate)

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Summary Public Assessment Report

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(budesonide, formoterol, formoterol fumarate dihydrate)

Pressurised inhalation, suspension, 80 mikrogram/2.25 mikrogram/actuation

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

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

What is Symbicort and what is it used for?

Symbicort is an inhaler that is used to treat asthma in adults and adolescents aged 12-17 years. It contains two different medicines: budesonide and formoterol fumarate dihydrate.

How does Symbicort work?

- 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 beta2 adrenoceptor agonists’ or ‘bronchodilators’. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

How is Symbicort used?

The pharmaceutical form of Symbicort is pressurised inhalation, suspension for inhalation.

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 in Sweden.

What benefits of Symbicort have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Symbicort is effective in treating asthma in adults and adolescents aged 12-17 years.

What are the possible side effects of Symbicort?

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

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

Why is Symbicort approved?

This medicine contains the same active substances as the already authorised Symbicort, 160/4.5 micrograms/actuation, pressurised inhalation, suspension, but is given by a new strength. The company has provided additional own data to demonstrate the safety and efficacy of the new formulation. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Symbicort'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 Symbicort?

A risk management plan has been developed to ensure that Symbicort 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 Symbicort, 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 Symbicort

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

This summary was last updated in 2021-02.