LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Foracort
(budesonide, formoterol fumarate dihydrate)

SE/H/2511/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Foracort
budesonide, formoterol fumarate dihydrate

Pressurised inhalation, suspension, 160 micrograms/4,5 micrograms/actuation

This is a summary of the public assessment report (PAR) for Foracort. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Foracort and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Symbicort.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

The product is used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 and older. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

How does Foracort work?

The product 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 Foracort used?
The pharmaceutical form 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 Foracort have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Symbicort, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Foracort?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Foracort approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Symbicort, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Foracort?

A risk management plan has been developed to ensure that the product 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, 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 Foracort

The full PAR for Foracort can be found on the following website: MRI - Home. For more information about treatment with Foracort, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-07