LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salmeterol/Flutikason ELC Group (fluticasone propionate, salmeterol xinafoate)

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Inhalation powder, pre-dispensed, 50 mikrogram/250 mikrogram/dos, 50 mikrogram/500 mikrogram/dos

This is a summary of the public assessment report (PAR) for Salmeterol/Flutikason ELC Group. 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 Salmeterol/Flutikason ELC Group and what is it used for?

Salmeterol/Flutikason ELC Group 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 Seretide Diskus mite.

Salmeterol/Flutikason ELC Group is used to help prevent breathing problems such as asthma and Chronic Obstructive Pulmonary Disease (COPD).

Salmeterol/Flutikason ELC Group is indicated in the regular treatment of asthma where use of a combination product (long- acting β2 agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 agonist
  or
- patients already adequately controlled on both inhaled corticosteroid and long-acting β2 agonist

The product is indicated for the symptomatic treatment of patients with COPD, with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.

How does Salmeterol/Flutikason ELC Group work?

Salmeterol/Flutikason ELC Group contains salmeterol and fluticasone propionate which have differing modes of action.
Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

How is Salmeterol/Flutikason ELC Group used?

The pharmaceutical form is Inhalation powder, pre-dispensed 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 Salmeterol/Flutikason ELC Group have been shown in studies?

Because Salmeterol/Flutikason ELC Group is a hybrid application and is considered to be therapeutically equivalent to the reference product Seretide Diskus mite, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Salmeterol/Flutikason ELC Group?

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 Salmeterol/Flutikason ELC Group approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Seretide Diskus mite, 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 Salmeterol/Flutikason ELC Group?

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 Salmeterol/Flutikason ELC Group

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

This summary was last updated in 2023-03.