LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salmeterol/Fluticasone Genetic (fluticasone propionate, salmeterol xinafoate)

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Inhalation powder, pre-dispensed, 50/100 microgram/dose, 50/250 microgram/dose, 50/500 microgram/dose

This is a summary of the public assessment report (PAR) for Salmeterol/Fluticasone Genetic. 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/Fluticasone Genetic 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 Seretide Diskus mite (for 50/100 microgram/dose), Seretide Diskus (for 50/250 microgram/dose), and Seretide Diskus forte (for 50/500 microgram/dose), respectively.

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

The product is used to help prevent breathing problems such as asthma and Chronic Obstructive Pulmonary Disease (COPD). It helps stopping breathlessness and wheeziness coming on.

The product is **not** to be used to relieve a sudden attack of breathlessness or wheezing. In such case, a fast-acting 'reliever' ('rescue') inhaler, such as salbutamol, should be used instead. A fast-acting 'rescue' inhaler should always be carried along with this product, in case it is needed.

How does Salmeterol/Fluticasone Genetic work?

The product contains two medicines, salmeterol and fluticasone propionate:
- Salmeterol is a long-acting bronchodilator. Bronchodilators help keeping the airways in the lungs open for easier breathing (ventilation). The effect lasts for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

How is Salmeterol/Fluticasone Genetic used?

The pharmaceutical form is ´inhalation powder, pre-dispensed´, for oral use through 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/Fluticasone Genetic have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Seretide Diskus (mite / -- / forte, respectively, depending on the dose), the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Salmeterol/Fluticasone Genetic?

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/Fluticasone Genetic 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 Seretide Diskus (mite / -- / forte, respectively, depending on the dose), 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/Fluticasone Genetic?

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/Fluticasone Genetic

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

This summary was last updated in 2024-10.