LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salmeterol/ Fluticasone Wellnex (salmeterol xinafoat/fluticasone propionate)

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Salmeterol/Fluticasone Wellnex

(salmeterol xinafoat/fluticasone propionate)

Inhalation powder, pre-dispensed, 50/500 µg

This is a summary of the public assessment report (PAR) for Salmeterol/Fluticasone Wellnex. It explains how Salmeterol/Fluticasone Wellnex 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 Salmeterol/Fluticasone Wellnex.

For practical information about using Salmeterol/Fluticasone Wellnex, patients should read the package leaflet or contact their doctor or pharmacist.

What is Salmeterol/Fluticasone Wellnex and what is it used for?

Salmeterol/Fluticasone Wellnex is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The company has provided additional own data to demonstrate therapeutic equivalence between Salmeterol/Fluticasone Wellnex and the reference medicine.

The reference medicine for Salmeterol/Fluticasone Wellnex is Seretide Diskus. Salmeterol/Fluticasone Wellnex is used to treat adults and adolescents 12 years of age and older. Salmeterol/Fluticasone Wellnex is used to help prevent breathing problems such as severe asthma and to reduce the number of flare ups of Chronic Obstructive Pulmonary Disease (COPD) symptoms.

How does Salmeterol/Fluticasone Wellnex work?

Salmeterol/Fluticasone Wellnex contains two medicines, salmeterol and fluticasone propionate:

- 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/Fluticasone Wellnex used?

The pharmaceutical form of Salmeterol/Fluticasone Wellnex 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.

What benefits of Salmeterol/Fluticasone Wellnex have been shown in studies?

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

What are the possible side effects of Salmeterol/Fluticasone Wellnex?

For the full list of all side effects reported with Salmeterol/Fluticasone Wellnex, see section 4 of the package leaflet.

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

Why is Salmeterol/Fluticasone Wellnex approved?

This medicine is similar to a reference medicine containing the same active substance. The company has provided own data to demonstrate therapeutic equivalence between Salmeterol/Fluticasone Wellnex and the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Salmeterol/Fluticasone Wellnex'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 Salmeterol/Fluticasone Wellnex?

A risk management plan has been developed to ensure that Salmeterol/Fluticasone Wellnex 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 Salmeterol/Fluticasone Wellnex, 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 Wellnex

The marketing authorisation for Salmeterol/Fluticasone Wellnex was granted on 2019-12-18 in Sweden.

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

This summary was last updated in 2020-01.