LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salmeterol/Flutikason Devatis
(fluticasone propionate, salmeterol xinafoate)

SE/H/1683/03-04/X/06/G

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Pressurised inhalation, suspension, 25 mikrogram/125 mikrogram/dos

This is a summary of the public assessment report (PAR) for Salmeterol/Flutikason Devatis. 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 Devatis 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 substances.

The reference medicine for the product is Seretide Evohaler.

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

Salmeterol/Flutikason Devatis helps to prevent breathing problems such as asthma. The product is not suitable for children under the age of 12 years. For these patients a different inhaled salmeterol fluticasone product available in lower strength (25/50 microgram) should be used.

How does Salmeterol/Flutikason Devatis work?

Salmeterol/Flutikason Devatis 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/Flutikason Devatis 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 Salmeterol/Flutikason Devatis have been shown in studies?

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

What are the possible side effects from Salmeterol/Flutikason Devatis?

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 Devatis 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 Seretide Evohaler. Therefore, the Swedish Medical Products Agency decided that, as for Seretide Evohaler, 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 Devatis?

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 Devatis

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

This summary was last updated in 2022-08.