

Summary Public Assessment Report

Salmeterol/Flutikason Devatis (salmeterol, fluticasone propionate)

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Salmeterol/Flutikason Devatis
(salmeterol, fluticasone propionate)

25 microgram/250 microgram/actuation, pressurised inhalation, suspension

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

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

What is Salmeterol/Flutikason Devatis and what is it used for?

Salmeterol/Flutikason Devatis is a 'hybrid medicine'. This means that it is similar (*therapeutically equivalent*) to a reference medicine containing the same active substance.

The reference medicine for Salmeterol/Flutikason Devatis is Seretide Evohaler.

Salmeterol/Flutikason Devatis helps to prevent breathing problems such as asthma. It is not suitable for children under the age of 12 years. For these patients a different inhaled salmeterol fluticasone product available in lower strength (25/125 microgram or 25/50 microgram) should be used.

How does Salmeterol/Flutikason Devatis work?

This medicine contains two active substances. 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 of Salmeterol/Flutikason Devatis 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.

What benefits of Salmeterol/Flutikason Devatis have been shown in studies?

Because Salmeterol/Flutikason Devatis 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 of Salmeterol/Flutikason Devatis?

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

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

Why is Salmeterol/Flutikason Devatis approved?

This medicine is similar to a reference medicine containing the same active substance. The company has provided additional own data to demonstrate the safety and efficacy of Salmeterol/Flutikason Devatis regarding this difference from the reference medicine. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that the benefits of Salmeterol/Flutikason Devatis 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/Flutikason Devatis?

A risk management plan has been developed to ensure that Salmeterol/Flutikason Devatis 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/Flutikason Devatis, 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 marketing authorisation for Salmeterol/Flutikason Devatis was granted on 2019-01-25 in Sweden.

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 2019-02