

Summary Public Assessment Report

Salmeterol/Fluticasone Cipla (salmeterol xinafoate, fluticasone propionate)

SE/H/1208/01-02/E/01

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Pressurised inhalation, suspension, 25 mikrogram/125 mikrogram/dos, 25 mikrogram/250 mikrogram/dos

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

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

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

Salmeterol/Fluticasone Cipla 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 the safety and efficacy of Salmeterol/Fluticasone Cipla regarding this difference from the reference medicine.

The reference medicine for Salmeterol/Fluticasone Cipla is Seretide Evohaler. Salmeterol/Fluticasone Cipla is used in the treatment of asthma, swelling and irritation of the lungs and helps keeping the airways open.

How does Salmeterol/Fluticasone Cipla work?

Salmeterol/Fluticasone Cipla helps to stop breathlessness and wheeziness coming on, however it should not be used to relieve a sudden attack of breathlessness or wheezing. Salmeterol produces a longer duration of the opening of the airways. Fluticasone has an anti-inflammatory action within the lungs, resulting in reduced symptoms of asthma.

How is Salmeterol/Fluticasone Cipla used?

The pharmaceutical form of Salmeterol/Fluticasone Cipla is pressurised inhalation, suspension.

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 Cipla have been shown in studies?

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

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

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

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

Why is Salmeterol/Fluticasone Cipla 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/Fluticasone Cipla 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 Salmeterol/Fluticasone Cipla'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 Cipla?

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

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

This summary was last updated in 2020-07.