

Summary Public Assessment Report

Sipova Airmaster

(salmeterol xinafoate, fluticasone propionate)

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

This is a summary of the public assessment report (PAR) for Sipova Airmaster. It explains how Sipova Airmaster 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 Sipova Airmaster.

For practical information about using Sipova Airmaster, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sipova Airmaster and what is it used for?

Sipova Airmaster 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 Sipova Airmaster regarding this difference from the reference medicine.

The reference medicine for Sipova Airmaster is Seretide Diskus. Sipova Airmaster is used to treat adults and adolescents 12 years of age and older. Sipova Airmaster 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 Sipova Airmaster work?

Sipova Airmaster 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 Sipova Airmaster used?

The pharmaceutical form of Sipova Airmaster 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 in Sweden.

What benefits of Sipova Airmaster have been shown in studies?

Because Sipova Airmaster 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 Sipova Airmaster?

For the full list of all side effects reported with Sipova Airmaster, see section 4 of the package leaflet.

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

Why is Sipova Airmaster approved?

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

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Sipova Airmaster'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 Sipova Airmaster?

A risk management plan has been developed to ensure that Sipova Airmaster 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 Sipova Airmaster, 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 Sipova Airmaster

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

This summary was last updated in 2020-10.