

Summary Public Assessment Report

Campona 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 Campona Airmaster. It explains how Campona 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 Campona Airmaster.

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

What is Campona Airmaster and what is it used for?

Campona 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 Campona Airmaster regarding this difference from the reference medicine.

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

Campona 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 Campona Airmaster used?

The pharmaceutical form of Campona 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 Campona Airmaster have been shown in studies?

Because Campona 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 Campona Airmaster?

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

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

Why is Campona 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 Campona Airmaster and the reference medicine.

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

A risk management plan has been developed to ensure that Campona 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 Campona 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 Campona Airmaster

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

This summary was last updated in 2020-10.