LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fusacomb Easyhaler
(fluticasone propionate, salmeterol xinafoate)

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Summary Public Assessment Report

Fusacomb Easyhaler

(fluticasone propionate, salmeterol xinafoate)

Inhalation powder, 50 microgram/500 microgram/dose

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

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

What is Fusacomb Easyhaler and what is it used for?

Fusacomb Easyhaler is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is given with a different inhaler.

The company has provided data to demonstrate that the performance of the drugs in this inhaler is similar to the reference product (so called therapeutic equivalence).

The reference medicine for Fusacomb Easyhaler is Seretide Diskus forte.
Fusacomb Easyhaler is used in the treatment of breathing problems such as:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD)

How does Fusacomb Easyhaler work?

Fusacomb Easyhaler 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 Fusacomb Easyhaler used?

The pharmaceutical form of Fusacomb Easyhaler is inhalation powder 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 Fusacomb Easyhaler have been shown in studies?

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

What are the possible side effects of Fusacomb Easyhaler?

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

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

Why is Fusacomb Easyhaler approved?

This medicine is similar to a reference medicine containing the same active substance, but is given with a different inhaler. Fusacomb Easyhaler has been shown therapeutic equivalence to the reference product Seretide Diskus forte.
As therapeutic equivalence was shown, the Medical Products Agency in Sweden recommended that Fusacomb Easyhaler can be approved for use.

What measures are being taken to ensure the safe and effective use of Fusacomb Easyhaler?

A risk management plan has been developed to ensure that Fusacomb Easyhaler 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 Fusacomb Easyhaler, 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 Fusacomb Easyhaler

The marketing authorisation for Fusacomb Easyhaler was granted on 2018-06-08 in Sweden.

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

This summary was last updated in 2018-08.