LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fluticasone Elpen
(fluticasone propionate)

SE/H/1765/01-02/DC

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Summary Public Assessment Report

Fluticasone Elpen

(fluticasone propionate)

Inhalation powder, pre-dispensed
250 microgram/dose and 500 microgram/dose

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

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

What is Fluticasone Elpen and what is it used for?

Fluticasone Elpen 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 Fluticasone Elpen is Flutide Diskus 250 mikrogram. Fluticasone Elpen is used in the treatment of asthma and COPD (Chronic Obstructive Pulmonary Disease) together with a long-acting bronchodilator. The full effect is first observed after several days of regular treatment. Fluticasone Elpen does not provide rapid relief in the event of acute asthma attacks. If such event occurs, a quick and short-acting bronchodilator medicine should be used.

How does Fluticasone Elpen work?

Fluticasone Elpen is a cortisone preparation that counteracts inflammation and allergy directly in the lungs. Reducing inflammation can prevent asthma attacks.

Fluticasone Elpen is used as a regular treatment for asthma and COPD (Chronic Obstructive Pulmonary Disease) together with a long-acting bronchodilator. The full effect is first observed after several days of regular treatment. Fluticasone Elpen does not provide rapid relief in the event of acute asthma attacks. If such event occurs, a quick and short-acting bronchodilator medicine should be used. If the treatment does not give the desired effect, consult a doctor.

How is Fluticasone Elpen used?

The pharmaceutical form of Fluticasone Elpen 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 Fluticasone Elpen have been shown in studies?

Because Fluticasone Elpen is a hybrid application and is considered to be therapeutically equivalent, to the reference product Flutide Diskus 250 mikrogram, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Fluticasone Elpen?

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

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

Why is Fluticasone Elpen approved?

This medicine 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).

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

A risk management plan has been developed to ensure that Fluticasone Elpen 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 Fluticasone Elpen, 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 Fluticasone Elpen

The marketing authorisation for Fluticasone Elpen was granted on 2019-03-28 in Sweden.

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

This summary was last updated in 2019-04