LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Icsori
fluticasone propionate

SE/H/1284/01-02/E/01

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Summary Public Assessment Report

Icsori
fluticasone propionate

Pressurised inhalation, suspension, 125 microgram per activation, 250 microgram per activation.

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

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

What is Icsori and what is it used for?

Icsori is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Icsori is Flutide Evohaler.

The company has provided additional own data to demonstrate therapeutic equivalence between Icsori and the reference medicine.

Icsori is used to prevent asthma attacks in people who need regular treatment.

How does Icsori work?

This medicine contains the active substance fluticasone propionate which belongs to a group of medicines called corticosteroids. Icsori works by reducing inflammation in the lungs. This helps to prevent asthma attacks in people who need regular treatment. It takes 4-7 days for this medicine to work and it is very important that it is used regularly.

Icsori will not help treat sudden asthma attacks. A different medicine is used for treating sudden attacks.

How is Icsori used?

The pharmaceutical form of Icsori is pressurised inhalation, suspension for inhalation use.

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 Icsori have been shown in studies?

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

What are the possible side effects from Icsori?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Icsori approved?

It was concluded that, in accordance with EU requirements, Icsori has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine Flutide Evohaler. Therefore, the Swedish Medical Products Agency decided that, as for Flutide Evohaler, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Icsori 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 Icsori, 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 Icsori

The full PAR for Icsori can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Icsori

This summary was last updated in 2022-01.