

Summary Public Assessment Report

Ciclesonide Orifarm (ciclesonide)

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ciclesonide

Pressurised inhalation, solution, 80 microgram/dose, 160 microgram/dose, 320 microgram/dose

This is a summary of the public assessment report (PAR) for Ciclesonide Orifarm. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ciclesonide Orifarm and what is it used for?

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

The reference medicine for the product is Alvesco.

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

The product is used to treat persistent asthma in adult and adolescent patients (12 years old and older).

How does Ciclesonide Orifarm work?

Ciclesonide Orifarm is a clear and colorless aerosol spray for you to breathe in through your mouth and into your lungs. It is a preventive medication (corticosteroid) that has to be taken every day and which becomes active only after it has been inhaled into your lungs.

How is Ciclesonide Orifarm used?

The pharmaceutical form is pressurised inhalation, solution.

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 Ciclesonide Orifarm have been shown in studies?

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

What are the possible side effects from Ciclesonide Orifarm?

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 Ciclesonide Orifarm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Alvesco, 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 Ciclesonide Orifarm?

A risk management plan has been developed to ensure that the product 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, 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 Ciclesonide Orifarm

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

This summary was last updated in 2024-10.