LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Arquist
(fluticasone propionate)

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Arquist

fluticasone propionate
inhalation, suspension

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

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

What is Arquist and what is it used for?

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

The reference medicine for Arquist is Flutide Evohaler. Arquist is used for the regular treatment of asthma in adult and adolescents over 12 years of age.

How does Arquist work?

This medicine contains the active substance fluticasone propionate which belongs to a group of medicines called corticosteroids. Arquist 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 also when you do not have symptoms.

How is Arquist used?

The pharmaceutical form of Arquist is inhalation, suspension.

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 Arquist have been shown in studies?

Because Arquist 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 of Arquist?

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

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

Why is Arquist approved?

This medicine 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 Arquist regarding this difference from the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Arquist'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 Arquist?

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

The marketing authorisation for Arquist was granted on 2016-12-22 in Sweden.

The full PAR for Arquist can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Arquist, please read the package leaflet on https://lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=20151103000061&type=product or contact your doctor or pharmacist.

This summary was last updated in 2016-12-22.