LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Solafid
(fluticasone propionate, azelastine hydrochloride)

SE/H/2427/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Solafid
fluticasone propionate, azelastine hydrochloride

Nasal spray, suspension, 125 mikrogram + 50 mikrogram per actuation

This is a summary of the public assessment report (PAR) for Solafid.
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 Solafid 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 Dymista.

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

The product is used to relieve the symptoms of moderate to severe seasonal and perennial allergic rhinitis if the use of either intranasal antihistamine or corticosteroid alone is not considered sufficient.
Seasonal and perennial allergic rhinitis are allergic reactions to substances such as pollen (hayfever), house mites, moulds, dust or pets.
Solafid relieves the symptoms of allergies, for example: runny nose, post nasal drip, sneezing and itchy or blocked nose.

How does Solafid work?

Solafid contains two active substances: azelastine hydrochloride and fluticasone propionate.

- Azelastine hydrochloride belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction – thus reducing symptoms of allergic rhinitis.
- Fluticasone propionate belongs to a group of medicines called corticosteroids which reduces inflammation.

How is Solafid used?

The pharmaceutical form is nasal spray, suspension, for nasal 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 Solafid have been shown in studies?

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

What are the possible side effects from Solafid?

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 Solafid approved?

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

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 Solafid

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

This summary was last updated in 2024-06.