

Summary Public Assessment Report

Olopatadin Orifarm (olopatadine hydrochloride)

SE/H/2075/01/DC

Summary Public Assessment Report

Olopatadin Orifarm
olopatadine hydrochloride

Eye drops, solution, 1 mg/ml

This is a summary of the public assessment report (PAR) for Olopatadin 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 Olopatadin 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 Opatanol, 1 mg/mL, eye drops, solution.

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

The product is used for the treatment of signs and symptoms of seasonal allergic conjunctivitis.

How does Olopatadin Orifarm work?

Olopatadin Orifarm is a medicine for treatment of allergic conditions of the eye. It works by reducing the intensity of the allergic reaction.

How is Olopatadin Orifarm used?

The pharmaceutical form is eye drops, solution for ocular 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 Olopatadin Orifarm have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Opatanol, 1 mg/mL, eye drops, solution, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Olopatadin 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 Olopatadin 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 Opatanol, 1 mg/mL, eye drops, solution. Therefore, the Swedish Medical Products Agency decided that, as for Opatanol, 1 mg/mL, eye drops, solution, 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 Olopatadin 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 Olopatadin Orifarm

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

This summary was last updated in 2022-09.