

Summary Public Assessment Report
non-generics

Olopatadine UNIMED PHARMA 1mg/ml
olopatadine hydrochloride

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Olopatadine UNIMED PHARMA 1 mg/ml eye drops, solution

Olopatadine, eye drops solution, 1 mg/ml

This is a summary of the public assessment report (PAR) for Olopatadine UNIMED PHARMA 1 mg/ml. It explains how Olopatadine UNIMED PHARMA 1 mg/ml 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 Olopatadine UNIMED PHARMA 1 mg/ml.

For practical information about using Olopatadine UNIMED PHARMA 1 mg/ml, patients should read the package leaflet or contact their doctor or pharmacist.

What is Olopatadine UNIMED PHARMA and what is it used for?

Olopatadine UNIMED PHARMA is a ‘hybrid generic medicine’. This means that it is similar to a reference medicine containing the same active substance, but bioequivalence cannot be demonstrated through bioavailability studies.

The company has provided additional data to demonstrate the safety and efficacy of Olopatadine UNIMED PHARMA regarding this difference from the reference medicine.

The reference medicine for Olopatadine UNIMED PHARMA 1mg/ml is Opatanol 1 mg/ml eye drops, solution.

Olopatadine UNIMED PHARMA is used for the treatment of signs and symptoms of seasonal allergic conjunctivitis.

Olopatadine UNIMED PHARMA is a sterile solution that does not contain a preservative.

How does Olopatadine UNIMED PHARMA 1 mg/ml work?

Olopatadine UNIMED PHARMA is a medicine for treatment of allergic conditions of the eye. It works by reducing the intensity of the allergic reaction.

Olopatadine UNIMED PHARMA is indicated in adults, adolescents aged 12 to 18 years and children aged 3 to 12 years.

How is Olopatadine UNIMED PHARMA 1 mg/ml used?

The pharmaceutical form of Olopatadine UNIMED PHARMA 1 mg/ml is eye drops, solution and the route of administration is ocular use only.

The recommended dose is one drop in the eye or eyes, twice a day – morning and evening.

Please read section 3 of the PL 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 Olopatadine UNIMED PHARMA 1 mg/ml have been shown in studies?

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

What are the possible side effects from Olopatadine UNIMED PHARMA 1 mg/ml?

The most common side effects with Olopatadine UNIMED PHARMA (which may affect up to 1 in 10 people) are

Effects in the eye: eye pain, eye irritation, dry eye, abnormal eye sensation, eye discomfort

General side effects: headache, fatigue, dry nose, bad taste

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

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

Why is Olopatadine UNIMED PHARMA 1 mg/ml approved?

The State Institute for Drug Control decided that Olopatadine UNIMED PHARMA'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 Olopatadine UNIMED PHARMA?

A risk management plan has been developed to ensure that Olopatadine UNIMED PHARMA 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 Olopatadine UNIMED PHARMA, 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 Olopatadine UNIMED PHARMA 1 mg/ml

The marketing authorisation for Olopatadine UNIMED PHARMA 1 mg/ml was granted on 13.3.2020.

The full PAR for Olopatadine UNIMED PHARMA 1 mg/ml can be found on the [ŠÚKL website](#).

For more information about treatment with Olopatadine UNIMED PHARMA 1 mg/ml, read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 05-2020.