LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ultracortenol
(prednisolone pivalate)

SE/H/1794/01/MR

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Eye ointment, 5 mg/g

This is a summary of the public assessment report (PAR) for Ultracortenol. 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 Ultracortenol and what is it used for?

The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Ultracortenol is used in adults to treat a severe inflammation in the anterior part of the eye that has not occurred due to an infection.

How does Ultracortenol work?

Ultracortenol contains the active substance prednisolone pivalate. Prednisolone pivalate is a glucocorticoid (a steroid) with a strong anti-inflammatory effect. It inhibits the release of inflammatory substances in the body, thereby preventing signs of inflammation, e.g. swelling, dilation of blood vessels and scarring.

How is Ultracortenol used?

The pharmaceutical form is eye ointment 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 Ultracortenol have been shown in studies?

As prednisolone is a well-known substance, and its use in the treatment of severe inflammation in the anterior part of the eye that has not occurred due to an infection is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of prednisolone in the above-mentioned treatment.

What are the possible side effects from Ultracortenol?

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 Ultracortenol approved?

The Swedish Medical Products Agency decided that 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 Ultracortenol?

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 Ultracortenol

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

This summary was last updated in 2022-09.