LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oviderm
(propylene glycol)

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Summary Public Assessment Report

Oviderm

(propylene glycol)

Cream, 250 mg/g

This is a summary of the public assessment report (PAR) for Oviderm® 250 mg/g cream. It explains how Oviderm 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 Oviderm.

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

What is Oviderm and what is it used for?

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

Oviderm is used for the treatment of dry skin.

How does Oviderm work?

Oviderm is an emollient cream containing the active substance propylene glycol (25%). Propylene glycol has water-binding properties and some antimicrobial effect, on certain bacteria and fungae.

How is Oviderm used?

The pharmaceutical form of Oviderm is cream for cutaneous 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 be obtained without a prescription.

What benefits of Oviderm have been shown in studies?

As propylene glycol is a well-known substance, and its use in the treatment of dry skin is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of propylene glycol in the treatment of dry skin.

What are the possible side effects of Oviderm?

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

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

Why is Oviderm approved?

The use of Oviderm in the treatment of dry skin is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that the benefits of Oviderm 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 Oviderm?

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

The marketing authorisation for Oviderm was granted on2017-09-26 in Sweden.

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

This summary was last updated in 2017-10.