

Summary Public Assessment Report

Miniderm Duo (glycerol, urea)

SE/H/2078/01/DC

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Miniderm Duo
glycerol, urea

Cream, 20 mg/g + 200 mg/g

This is a summary of the public assessment report (PAR) for Miniderm Duo. It explains how Miniderm Duo 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 Miniderm Duo.

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

What is Miniderm Duo and what is it used for?

Miniderm Duo is an emollient and protective cream that contains urea and glycerol.

Miniderm Duo is used for the moisturising treatment of dry skin in adults, adolescents and children of all ages.

How does Miniderm Duo work?

Miniderm Duo cream contains 20 % glycerol and 2 % urea in an emollient, self-preserved cream base. The water-binding and barrier strengthening ability of Miniderm Duo contributes to normalization of dry skin. The composition of the Miniderm Duo cream base delivers urea and glycerol to the skin and enhance their therapeutic effect, i.e. the skin hydrating, itch reducing and protective effect.

How is Miniderm Duo used?

The pharmaceutical form of Miniderm Duo 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 in Sweden.

What benefits of Miniderm Duo have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Miniderm Duo is effective in treating dry skin in adults, adolescents and children of all ages.

What are the possible side effects of Miniderm Duo?

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

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

Why is Miniderm Duo approved?

It was noted that the effect of Miniderm Duo in the treatment of dry skin in adults, adolescents and children of all ages was significantly better than treatment with placebo. The application is supported by literature data, and by a clinical trial determining the superiority of Miniderm Duo compared to no treatment (placebo), and two reference treatments.

Therefore, the Medical Products Agency in Sweden decided that Miniderm Duo'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 Miniderm Duo?

A risk management plan has been developed to ensure that Miniderm Duo 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 Miniderm Duo, 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 Miniderm Duo

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

This summary was last updated in 2021-05.