

Summary Public Assessment Report

Miniderm Comp (glycerol, urea)

SE/H/2080/01/DC

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Miniderm Comp
glycerol, urea

Cream, 20 mg/g + 200 mg/g

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

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

What is Miniderm Comp and what is it used for?

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

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

How does Miniderm Comp work?

Miniderm Comp cream contains 20 % glycerol and 2 % urea in an emollient, self-preserved cream base. The water-binding and barrier strengthening ability of Miniderm Comp contributes to normalization of dry skin. The composition of the Miniderm Comp 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 Comp used?

The pharmaceutical form of Miniderm Comp 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 Comp have been shown in studies?

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

What are the possible side effects of Miniderm Comp?

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

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

Why is Miniderm Comp approved?

It was noted that the effect of Miniderm Comp 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 Comp compared to no treatment (placebo), and two reference treatments.

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

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

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

This summary was last updated in 2021-05.