

Summary Public Assessment Report

Karbamid/Glycerol ACO (glycerol, urea)

SE/H/2079/01/DC

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Karbamid/Glycerol ACO
glycerol, urea

Cream, 20 mg/g + 200 mg/g

This is a summary of the public assessment report (PAR) for Karbamid/Glycerol ACO. It explains how Karbamid/Glycerol ACO 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 Karbamid/Glycerol ACO.

For practical information about using Karbamid/Glycerol ACO, patients should read the package leaflet or contact their doctor or pharmacist.

What is Karbamid/Glycerol ACO and what is it used for?

Karbamid/Glycerol ACO is an emollient and protective cream that contains urea and glycerol.

Karbamid/Glycerol ACO is used for the moisturising treatment of dry skin in adults, adolescents and children of all ages

How does Karbamid/Glycerol ACO work?

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

The pharmaceutical form of Karbamid/Glycerol ACO 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 Karbamid/Glycerol ACO have been shown in studies?

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

What are the possible side effects of Karbamid/Glycerol ACO?

For the full list of all side effects reported with Karbamid/Glycerol ACO, see section 4 of the package leaflet.

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

Why is Karbamid/Glycerol ACO approved?

It was noted that the effect of Karbamid/Glycerol ACO 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 Karbamid/Glycerol ACO compared to no treatment (placebo), and two reference treatments.

Therefore, the Medical Products Agency in Sweden decided that Karbamid/Glycerol ACO'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 Karbamid/Glycerol ACO?

A risk management plan has been developed to ensure that Karbamid/Glycerol ACO 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 Karbamid/Glycerol ACO, 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 Karbamid/Glycerol ACO

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

This summary was last updated in 2021-05.