

Summary Public Assessment Report

Curemid (urea)

SE/H/2136/01/MR

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Curemid
urea

Cream, 50 mg/g

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

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

What is Curemid and what is it used for?

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

Curemid can be used by adults and children as moisturizing treatment of dry skin of various origins.

How does Curemid work?

Carbamide has water binding properties, which contribute to normalization of dry skin.

How is Curemid used?

The pharmaceutical form of Curemid 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 Curemid have been shown in studies?

As carbamid is a well-known substance, and its use as moisturizing treatment of dry skin of different origin is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of carbamid for the approved use.

What are the possible side effects from Curemid?

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 Curemid approved?

The Swedish Medical Products Agency decided that Curemid's 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 Curemid?

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

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

This summary was last updated in 2022-05.