LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Karbamid Evolan
(urea)

SE/H/1954/01/MR

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Karbamid Evolan

(urea)

Cream, 50mg/g

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

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

What is Karbamid Evolan and what is it used for?

Karbamid Evolan is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Karbamid Evolan is Canoderm 5% cream. Karbamid Evolan is used to moisturise dry skin of different origin and to prevent relapses of atopic eczema.

How does Karbamid Evolan work?

Karbamid Evolan is a white emollient cream containing 5 % urea. The water-binding ability of urea contributes to normalization of dry skin.

How is Karbamid Evolan used?

The pharmaceutical form of Karbamid Evolan is a cream for topical 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 Evolan have been shown in studies?

Because Karbamid Evolan is a hybrid application and is considered to be therapeutically equivalent, to the reference product Canoderm 5% cream, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Karbamid Evolan?

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

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

Why is Karbamid Evolan approved?

Since this medicine is similar to Canoderm 5% cream, which is already authorised, no new or unexpected safety concerns arose from this application. Therefore, the Medical Products Agency in Sweden decided that Karbamid Evolan'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 Evolan?

A risk management plan has been developed to ensure that Karbamid Evolan 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 Evolan, 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 Evolan

The marketing authorisation for Karbamid Evolan was granted on 2018-10-09 in Sweden.

The full PAR for Karbamid Evolan can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Karbamid Evolan, please read the package leaflet https://lakemedelsverket.se/LMF/Lakemedelsinformation/?nplid=20171102000039 or contact your doctor or pharmacist.

This summary was last updated in 2019-11.