SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Canoderm 5 % cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of cream contains: urea 50 mg.

Excipients: Ethyl parahydroxybenzoate, methyl parahydroxybenzoate, cetostearyl alcohol, propylene glycol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
White cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For moisturising of dry skin of different origin and for prevention of relapse of atopic eczema.

4.2 Posology and method of administration

For moisturising of dry skin of different origin: The cream can be applied when needed, preferably several times daily and always after contact with water.

For prevention of relapse of atopic eczema: Apply at least twice daily and preferably after contact with water.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings and precautions for use

Avoid application into eyes, nose, ears or to open wounds or mucous membranes.
Canoderm cream contains ethyl and methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).
Canoderm cream contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).
Canoderm cream contains propylene glycol.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Canoderm can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

There is no indication that Canoderm has any effect on the ability to drive or use machines.

4.8 Undesirable effects

The cream can give transient, local sensation of burning and heat. The face is most sensitive.

Common (>1/100)	*Skin:* Transient sensations of burning or heat

4.9 Overdose

Not relevant since the product is for cutaneous use only.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Protectives and emollients.
ATC code: D02AE01.

Mode of Action
Canoderm cream contains 5 % urea in an emollient cream base. The water-binding ability and barrier- strengthening ability of Canoderm contributes to normalization of dry skin and prevention of eczema relapses.Canoderm's cream base composition delivers urea into the skin and enhances its therapeutic efficacy i.e. the moisturizing, anti-pruritic and protective effects.

Clinical efficacy
The effect of Canoderm on the recurrence of atopic eczema was investigated in clinical studies.

In a randomized, double-blind controlled prospective comparative multi-center study, 198 subjects ≥18 years old, diagnosed with atopic dermatitis with visible atopic eczema of body surface area corresponding to a total area of at least the size of one palm were included in the study. Patients with eczema exclusively on the hands were excluded.
At the screening visit, study area eczemas were defined and the subjects treated their atopic eczemas with a strong glucocorticoid cream (mometasone furoate cream 0.1%) during a 3 weeks stabilization phase. In total 172 patients who became eczema free were randomized to maintenance treatment with either Canoderm cream or reference cream (containing no urea and with a neutral effect on the skin barrier). The maintenance phase lasted for 180± 14 days days or until eczema relapse.

At baseline, the median score of disease severity was 6.00 classified as moderate atopic dermatitis according to Rajka and Langeland and the number of relapses during the last year was 4.0.
The primary end-point was to examine the time between randomization and a subsequent event of relapse measured as a hazard ratio. The results of the study can be seen in the table below.

Table 1. Response to Canoderm Cream Treatment

	Canoderm cream	Reference cream	
Hazard Ratio (95% CI) compared to reference cream	0.634 (0.446, 0.901) (p=0.0110)		
Median Time to Relapse of Atopic Eczema (days) (Kaplan-Meier) Difference vs reference cream	22.0 (p=0.0129) 46.7 %	15.0	
Eczema Free Proportions at Day 180 (Kaplan-Meier)	26.4%	9.9%	
Absolute Risk Reduction			14.0%
Relative Risk Reduction			15.6%
Relative Risk			1.18

In another randomized controlled prospective multi-center clinical study, 55 patients with atopic eczema entered the study and treated defined atopic lesions with a strong steroid cream (betamethasone valerate 0.1% cream) during three weeks. Thereafter, 44 patients with cleared eczema were randomised to either maintenance therapy with Canoderm, or with no treatment. The time to relapse of the eczema was measured during 26 weeks. The study showed that Canoderm significantly increased the time to eczema relapse ($p<0.01$) compared to no treatment. During the maintenance therapy, 68% of the patients treated with Canoderm were eczema-free after 26 weeks (median time to relapse >180 days). In the untreated group, 32% were eczema-free for the corresponding period (median time to relapse 30 days). The absolute risk reduction was 36% and the relative risk reduction 53%.

The effect of Canoderm on the recurrence of hand eczema was investigated in a small clinical study. The median time to reappearance of eczema was 20 days in the Canoderm group compared to 2 days in the no treatment group ($p = 0.0401$).

5.2 Pharmacokinetic properties

The systemic absorption of urea has not been studied but is assumed to be negligible.

5.3 Preclinical safety data

No preclinical data avilable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides medium-chain
Polysorbate 60
Cetostearyl alcohol
Hydrogenated canola oil

Propylene glycol
Carbomer
Dimethicone
Hard paraffin
Glycerol polymetacrylate
Ethyl parahydroxybenzoate (E 214)
Methyl parahydroxybenzoate (E 218)
Sodium lactate solution
Lactic acid
Glyceryl stearate
Polyoxyethylene stearate
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Plastic tube (polyethylene), 30 g, with screw on cap.

Plastic tube (polyethylene), 100 g, with snap cap.

Plastic tube (polyethylene), 210 g, with snap cap.

Plastic jar (polypropylene) with pump, 380 g.

Plastic jar (polypropylene) with pump, 500 g.

Plastic jar (polypropylene), refill jar to plastic jar with pump, 500 g.

Twin pack 600g containing, plastic jar (polypropylene) with pump, 500 g + plastic tube (polyethylene), 100 g, with snap cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Before use of the pump jar, first remove the transport protection by pulling out the cotter and removing the collar. Press down the pump several times at the first time of use, in order to fill the pump.

Instructions for use for the refill jar:
How to move your pump
This is a refill jar. The pump from an emptied jar of Canoderm is moved to the refill jar.

- Wash your hands before changing pump.
- First, dry the outer parts of the pump and the cover.
- Remove the sealing ring around the cover on both the refill jar and the emptied jar with the pump (if this has not been done previously)
- Remove the outer cover from the refill jar. Let the inner cover stay.
- Remove the outer cover with the pump from the emptied jar. Leave the inner cover.
- AVOID touching the inside of the refill jar, the pump cover and the ascending pipe of the pump, in order not to deteriorate the durability of the product.
- Fix the pump's ascending pipe into the hole on the refill jar's inner cover.
- Press carefully the pump down into the jar until it stops. Then, fix the edges of the outer cover properly around the whole jar.
- Check that the cover has been fixed. The jar is ready to use. Pump a couple of times until cream is coming out.

7 MARKETING AUTHORISATION HOLDER

ACO Hud Nordic AB, Box 622, 194 26 UPPLANDS VÄSBY.

8 MARKETING AUTHORISATION NUMBER

13757

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1997-12-19/2007-12-19

10 DATE OF REVISION OF THE TEXT

2020-11-02