SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Miniderm Comp 20 mg/g + 200 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains: Urea 20 mg, Glycerol 200 mg

Excipients with known effect: cetostearyl alcohol
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream
White cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology
Adults, adolescents and children of all ages

The cream should be applied at least twice daily and preferably after contact with water.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Miniderm Comp cream contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to glycerol and urea is negligible. Miniderm Comp can be used during pregnancy.

Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to glycerol and urea is negligible. Miniderm Comp can be used during breast-feeding.

Fertility
No effects on fertility are anticipated, since systemic exposure to glycerol and urea is negligible.

4.7 Effects on ability to drive and use machines

Miniderm Comp has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse events are presented according to MedDRA system organ classification within each frequency area and after decreasing degree of severity:
Very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to <1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data)

System organ class	**Undesirable effect**
Skin and subcutaneous tissue disorders	
Common	Transient smarting, itching, stinging and redness.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.*

4.9 Overdose

There is no known risk of overdose of topical application of urea and glycerol

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Protectives and emollients.
ATC code: D02AE51

Mechanism of action
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

Pharmacodynamic study
The barrier strengthening effect of Miniderm Comp was investigated in a prospective multilateral randomised double-blind controlled clinical trial in 50 adult subjects with a history of atopic dermatitis. The reference creams were a paraffin-based cream and a cream with 20% glycerol as active substance.

The primary objective was to determine whether applying a new moisturizing cream (the test cream) for 4 weeks is superior in terms of skin barrier strengthening, when compared with (1) no treatment and (2) two reference creams in adults with a predisposition to a skin barrier defect. Emollients with skin barrier strengthening properties have been shown to prolong time to relapse of atopic eczema.

Outcome measures were Trans Epidermal Water Loss (TEWL) and redness after induction of skin irritation.

Skin barrier function improved after treatment with Miniderm Comp compared to untreated control, and compared to the two reference creams, as significantly lower response from an irritating agent, measured as reduction of Trans Epidermal Water Loss (TEWL), was found after 4 weeks of treatment.

Measurement of skin redness showed that Miniderm Comp was significantly better than untreated skin and skin treated with paraffin cream to protect from skin irritation. There was no significant difference in the effect of Miniderm Comp compared to 20% glycerol cream on skin redness.

Paediatric population
Miniderm Comp cream can be used for treatment of dry skin in children of all ages.

The European Medicines Agency has waived the obligation to submit the results of studies with Miniderm Comp in all subsets of the paediatric population in treatment of dry skin. See section 4.2 for information on paediatric use.

5.2 Pharmacokinetic properties

The systemic absorption of urea and glycerol has not been investigated but is assumed to be negligible.

5.3 Preclinical safety data

There are no other additional data of relevance to the prescriber than those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylene glycol (E1502)
Hydrogenated canola oil
Dexpanthenol
Triglycerides, medium-chain
Cetostearyl alcohol
Dimeticone (E 900)
Paraffin, hard (E905)
Glycerol monostearate (E471)
Macrogol stearate (E431)
Triacetin (E 1518)
Carbomer
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

27 months

The product should be used within 6 months of opening.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Plastic tube (polyethylene), 100 g, with flip-top snap cap (polypropylene).
Plastic jar (polypropylene), 500 g, with pump (polypropylene/polyethylene/steel).
Twin pack 600g containing plastic jar (polypropylene), 500g, with pump (polypropylene/polyethylene/steel) + plastic tube (polyethylene), 100 g, with snap cap (polypropylene).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

16/06/2022