SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Miniderm 20 % cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains: glycerol 200 mg.
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dry skin.

4.2 Posology and method of administration

The cream can be applied when needed, preferably several times daily and always 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

Risk of systemic effects has not been observed in clinical studies of this medicinal product.
Miniderm cream contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact eczema).
Miniderm cream contains ethyl and methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Formal interaction studies have not been performed.

4.6 Pregnancy and lactation

Miniderm can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Common (>1/100)	Transient smarting, itching, stinging and redness. However, Miniderm does not cause any more undesirable skin reactions than its vehicle.

4.9 Overdose

No known risk.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Protectives and emollients.
ATC code D02AX.

Miniderm cream contains 20 % glycerol in an emollient cream base with a fat content of 24 %. The water-binding ability of glycerol contributes to normalization of dry skin.
Miniderm cream can be used for treatment of dry skin in children and adults.

5.2 Pharmacokinetic properties

Formal pharmacokinetic studies have not been performed.

5.3 Preclinical safety data

There are no preclinical data considered relevant to the safety assessment beyond what has already been taken into consideration in other parts of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated canola oil
Cholesterol
Glycerol monostearate
Macrogol stearate
Cetostearylalcohol
Dimeticone
Light liquid paraffin
Hard paraffin
White soft paraffin
Ethyl parahydroxybenzoate (E 214)
Methyl parahydroxybenzoate (E218)
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3 years.

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 snap cap.

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

Plastic jar (polypropylene) with pump, 380 g.

Plastic jar (polypropylene) 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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

ACO HUD NORDIC AB, Box 622, 194 26 Upplands Väsby, Sweden

8 MARKETING AUTHORISATION NUMBER

16221

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2000-12-15 / 2010-12-15

10 DATE OF REVISION OF THE TEXT

2019-10-04