

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dermidex Dermatological Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine	1.20 % w/w
Aluminium chlorhydroxyallantoinate	0.25 % w/w
Chlorobutanol hemihydrate	1.00 % w/w
Cetrimide	0.50 % w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream

Smooth white homogenous cream with a characteristic perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antiseptic, anaesthetic, anti-irritant and emollient agent. For the treatment of mild pain caused by minor skin cuts, scratches and grazes (chapping) and soreness caused by detergents, soaps, deodorants and jewellery and bites and stings.

4.2 Posology and method of administration

Adults, the elderly and children over 4 years

Apply to the affected area every three hours.

Not suitable for children under four years of age.

4.3 Contraindications

Known sensitivity to the active constituents.

4.4 Special warnings and precautions for use

For external use only. Keep out of the reach of children. The product should not be used for longer than seven days without seeking medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No effects known in pregnancy and lactation. However as with all medicines use with caution.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Occasionally there have been reports of skin reactions with all such preparations.

4.9 Overdose

Overdose is unlikely. If large amounts are ingested, gastric lavage and supportive therapy may be indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol
Glyceryl monostearate
Isopropyl myristate
Light liquid paraffin
Phenoxyethanol
Sorbitol solution 70% (non-crystallising)
Stearyl alcohol
Perfume sport 11412C
Purified water

6.2 Incompatibilities

None known.

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

3g, 4g, 5g, 7.5g, 10g, 30g or 50g or product contained in:

- a) Lacquered convex tube with a low or medium density polyethylene cap in a carton.
- b) Aluminium tubes with a polyamide internal lacquer, a membrane nozzle fitted with full spiked white polyethylene cap in a carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
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8 MARKETING AUTHORISATION NUMBER

PA 610/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

August 2002