SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dermol Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid paraffin	10.0% w/w
Isopropyl myristate	10.0% w/w
Benzalkonium chloride	0.1% w/w
Chlorhexidine dihydrochloride	0.1% w/w

Excipients with known effect:
Cetostearyl alcohol

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Cream
White non-greasy topical emulsion

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

An antimicrobial emollient cream for the management of dry and pruritic skin conditions, especially eczema and dermatitis. The cream is suitable for direct application, and for use as a soap substitute.

4.2. Posology and method of administration

For external use only.

Before using the 500g pump bottle, turn the top of the pump dispenser anti-clockwise to unlock it.

For adults, the elderly, infants and children.
For application to the skin
Apply Dermol Cream to the affected areas as often as necessary.

For use as a soap substitute
Dermol Cream may also be used as a cleanser in the bath or shower, or for other toiletry purposes, instead of ordinary soap or shower gel.

4.3 Contraindications

Do not use in cases of known sensitivity (especially generalised allergic reaction) to any of the ingredients (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

Avoid contact with the eyes.
Take care to avoid slipping in the shower or bath, when using as a soap substitute.
Local skin reactions (e.g. contact dermatitis) to any of the ingredients are rare but possible in sensitive people.
There are literature reports of chlorhexidine compounds inducing hypersensitivity, including anaphylactic shock. The prevalence of this is not known, but is likely to be very rare. Dermol Cream should not be administered to anyone with a possible history of allergic reaction to a chlorhexidine compound (see sections 4.3 and 4.8).

Dermol Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5. Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Use during pregnancy and lactation is not expected to be associated with harmful effects to the mother as cutaneous absorption of benzalkonium chloride is minimal. When breast-feeding, if use on the nipples is necessary, apply sparingly and after feeds. Gently wipe away any remaining product before feeding your baby

4.7. Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Although the cream has been specially formulated for use on dry or problem skin, in the unlikely event of a reaction discontinue treatment.

Local skin reactions

These reactions are very rare (<1/10,000, based on spontaneous reporting) and may be irritant or allergic in nature. Reactions have been observed occasionally when used excessively as a leave-on application in areas of folded skin such as the anogenital area.

Serious generalised allergic reactions

Very rarely, hypersensitivity including anaphylactic reaction (see sections 4.3 and 4.4) is possible (based on literature for chlorhexidine-containing products).

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Excessive topical use is very unlikely to cause any untoward effects other than making the skin feel greasy.

In the event of a significant quantity being accidentally swallowed, nausea and vomiting may occur but serious effects are unlikely. Unless there are signs that give cause for concern, treatment should be conservative.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC Code: D02AX - Dermatologicals, other emollients and protectives.

Bacteria (especially *Staphylococcus aureus*) are implicated in the pathogenesis of inflammatory dry skin conditions such as atopic eczema or dermatitis.

Dermol Cream contains 20% of emollient oils in a non-greasy aqueous cream which also contains the well-known and effective antiseptics benzalkonium chloride and chlorhexidine dihydrochloride. Its antimicrobial properties assist in overcoming infection, whether from *Staph aureus*, the pathogen which often complicates eczema and associated pruritus, or secondary infection caused by scratching.

Massaged into the skin, the emollients, liquid paraffin and isopropyl myristate, permit rehydration of dry skin by forming an occlusive barrier within the skin surface, thus reducing drying from evaporation of water that diffuses from the underlying layers.

5.2. Pharmacokinetic properties

The active ingredients are presented in an aqueous cream and so are readily absorbed into the stratum corneum when the product is gently massaged over the areas of dry skin. The antiseptic ingredients are in intimate contact with the skin, and as they are in solution, their availability is optimal.

5.3. Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Glycerol
Macrogol cetostearyl ether (cetomacrogol)
Phenoxyethanol

Disodium phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Purified Water

6.2. Incompatibilities

None known

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°.

Replace cap after use.

6.5. Nature and contents of container

High density polyethylene squeezable bottle (500 g) with a polypropylene flip top cap.
High density polyethylene bottle (500 g) with a polypropylene metering pump.
High density polyethylene tube (100g) with a polypropylene screw cap.
Lacquered aluminium tube (30, 100g) with a polyethylene screw cap.

6.6. Instructions for use and handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Diomed Developments Limited
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Hertfordshire, SG4 7QR
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PL 00173/0171

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 May 2004

10 DATE OF REVISION OF THE TEXT

17/05/2024