SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Emulsiderm Emollient

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid Paraffin	25.0% w/w
Isopropyl Myristate	25.0% w/w
Benzalkonium Chloride (as Benzalkonium Chloride Solution)	0.5% w/w

For excipients see section 6.1.

3 PHARMACEUTICAL FORM

White cutaneous emulsion and bath additive.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

An antimicrobial bath emollient for use as an aid in the treatment of dry and pruritic skin conditions, especially eczema/dermatitis, ichthyosis or xeroderma. It permits the rehydration of the keratin by replacing lost lipids, and its antiseptic properties assist in overcoming secondary infection.

4.2. Posology and method of administration

Adults, including the elderly and children:

<u>For use in the bath:</u>

Add 7 - 30 ml Emulsiderm to a bath of warm water (more or less according to the size of the bath and individual patient requirements).

1 litre bottle - use graduated measuring cup provided.
50 - 500 ml bottles - ½ to 2 capfuls.

Soak for 5 - 10 minutes. Pat dry.

For application to the skin:

Rub a small amount of undiluted emollient into the dry areas of skin until absorbed.

4.3. Contraindications

Sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep away from the eyes.

For external use only.

Keep out of the sight and reach of children.

Take care to avoid slipping in the bath.

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

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.

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

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

For dry skin conditions it is important to add an emollient to the bath water. Emulsiderm contains 50% of oils emulsified in water as well as the well-known antiseptic, benzalkonium chloride which assists in overcoming secondary infection.

5.2. Pharmacokinetic properties

Emulsiderm contains 0.5% of the quaternary ammonium antiseptic, benzalkonium chloride. The large positively charged cation is readily adsorbed from the formulation onto negatively charged bacterial cell surfaces, thereby conferring substantial antimicrobial activity. Even at extended dilution, it is particularly effective against *Staphylococcus aureus*, a bacterium which is known to colonise the skin in large numbers in patients with eczema, especially atopic eczema. Apart from its emollient properties, Emulsiderm therefore also helps to prevent and overcome secondary infection which may exacerbate the eczematous condition.

5.3. Preclinical safety data

The safety and efficacy of the emollients (liquid paraffin and isopropyl myristate) and the antiseptic (benzalkonium chloride) in topical dosage forms have been well established over many years of widespread clinical usage.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan Stearate

Polysorbate 60

Industrial Methylated Spirit 95%

Purified Water

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months in unopened container.

6.4. Special precautions for storage

Do not store above 25°C. Always replace the cap after use.

6.5 Nature and contents of container

a) 30 ml high density polyethylene bottle fitted with low density polyethylene dispensing plug and Bakelite screw cap with low density polyethylene liner, or

50, 100, 125, 150, 200, 250, 300, 350 or 500 ml high density polyethylene bottle fitted with low density polyethylene dispensing plug and spigotted polypropylene screw cap, or

1000 ml high density polyethylene bottle and high density polyethylene screw cap with low density polyethylene liner.

For bottle sizes greater than the unit dose (30 ml), the screw cap incorporates a 10 ml or 15 ml measure, or a 30 ml measuring cup is supplied.

b) 10 ml paper/polyethylene/foil/polyethylene laminate sachet.
(Packaged into unit cartons in appropriate multiples to match the above bottle capacities)

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited,
T/A Dermal Laboratories,
Tatmore Place,
Hitchin,
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SG4 7QR
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

PL: 00173/0036.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/07/2009

10 DATE OF REVISION OF THE TEXT

15/02/2024