SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dermol 600 Bath Emollient.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium Chloride	0.5% w/w
Liquid Paraffin	25.0% w/w
Isopropyl Myristate	25.0% w/w

For excipients see Section 6.1.

3. PHARMACEUTICAL FORM

White 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

For use in the bath:

Adults, elderly and children:
Add up to 30 ml to a bath of warm water (more or less according to the size of the bath and individual patient requirements).
Infants:
Add up to 15 ml to a bath of warm water (more or less according to the size of the bath and individual patient requirements).

Soak for 5 - 10 minutes. Pat dry.

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. Pregnancy and lactation

No special precautions.

4.7. Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Although the bath 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.

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.

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. Dermol 600 Bath Emollient 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

Dermol 600 Bath Emollient 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, Dermol 600 Bath Emollient 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.
24 months for 1000 ml bottle once opened.

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) High density polyethylene BOTTLE (in pack sizes of 30, 50, 100, 125, 150, 200, 250, 300, 350, 500, 600 and 1000 ml) with polyethylene or Bakelite SCREW CAP, or polyethylene dispensing plug used in conjunction with a polypropylene SCREW CAP.

For BOTTLE sizes greater than the unit dose (30 ml), the SCREW CAP provides a 10, 15 or 20 ml measure, or a 30 ml measuring CUP is provided.

b). 10 ml laminate SACHET of paper (44 gsm) / polyethylene (10 gsm) / foil (8 mcm) and polyethylene (50 mcm).
(Packaged into unit cartons in appropriate multiples to match the above bottle capacities)

Supplied as original packs (OP).

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited,
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8. MARKETING AUTHORISATION NUMBER

PL: 00173/0155.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/07/2009

10 DATE OF REVISION OF THE TEXT

25/03/2020