Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Emulsiderm Emollient Bath Additive / Cutaneous Emulsion liquid paraffin 25% w/w, isopropyl myristate 25% w/w, benzalkonium chloride 0.5% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Bath additive or cutaneous emulsion
Pale green-blue oil-in-water emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an adjunct in the management of dry skin, by rehydration with antisepsis. Emulsiderm Emollient contains benzalkonium chloride. Benzalkonium chloride may be useful in preventing *Staphylococcus aureus*, a pathogen which often complicates atopic eczema and associated pruritus. Emulsiderm is specially formulated in a unique emulsion system optimised for convenient application to the skin, either via the patient's bath water or directly.

4.2 Posology and method of administration

Adults, including the elderly and children:

For use in the bath:

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

Soak for 5 to 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 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 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/hypersensitive 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 HPRA Pharmacovigilance. Website: www.hpra.ie.

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 *in vitro*, 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 atopic condition.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan stearate
Polysorbate 60
Industrial Methylated Spirit 95%
Methylthioninium chloride
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. Always replace the cap after use.

6.5 Nature and contents of container

a) i) 30 ml high density polyethylene bottle fitted with low density polyethylene dispensing plug and bakelite screw cap with low density polyethylene liner or,
ii) 50 and 300 ml high density polyethylene bottle fitted with low density polyethylene dispensing plug and spigotted polypropylene screw cap, or
iii) 1000 ml high density polyethylene bottle and screw cap with low density polyethylene liner.

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

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

Not all pack sizes may be marketed.

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

Dermal Laboratories (Ireland) Limited
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8 MARKETING AUTHORISATION NUMBER

PA23128/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 1982
Date of last renewal: 21 February 2009

10 DATE OF REVISION OF THE TEXT

March 2024