Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Psoriderm Emulsion 40% w/v Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Distilled Coal Tar 40.0% w/v.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Bath additive.
Buff-coloured liquid bath additive.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use topically as an aid in the treatment of subacute and chronic psoriasis.

4.2 Posology and method of administration

For adults, children and the elderly: add 30 ml of the emulsion to a standard bath of warm water. Soak for 5 minutes, pat dry.

4.3 Contraindications

Not to be used for acute, sore or pustular psoriasis or in the presence of infection.
Not to be used in cases of sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Do not use product undiluted.
Keep away from the eyes and broken or inflamed skin.
Replace cap after use.
Avoid spillage.
For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Local side-effects do not normally occur. In the rare event of skin irritation, acne-like eruptions or photosensitivity, discontinue treatment. Rarely, Psoriderm Emulsion Bath Additive may stain skin, hair or fabric.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

There are no known toxic effects resulting from excessive use of Psoriderm Bath Emulsion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D05AA

Coal tar has been used dermatologically for hundreds of years and has been shown to be safe and effective in the treatment of scaly skin conditions such as psoriasis. The British Pharmacopoeia contains monographs on coal tar and coal tar solution, and many formulations of coal tar are used in hospitals throughout the country. The coal tar used in Psoriderm Bath Emulsion has been specially distilled and is based on a neutral fraction which has been shown to be effective in the treatment of psoriasis.

The precise mechanism of action of coal tar is not understood, largely as a result of it comprising up to 10,000 components. There is evidence that topical application of coal tar improves psoriasis by reducing the excessive rate of mitotic epidermal cell division.

5.2 Pharmacokinetic properties

Dry scales, which are a common feature of psoriasis, generally reduce the effectiveness of topically applied treatments by reducing absorption of the active ingredient. An established means of overcoming this problem is to add a mild softening agent such as lecithin. In the case of Psoriderm Bath Emulsion, however, no such softening agent is included because the dosage and administration regime involves prolonged soaking (5 minutes) in a warm water emulsion which achieves a similar effect.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 20

Trolamine
Phenoxyethanol
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.

6.5 Nature and contents of container

Amber glass bottle and polypropylene screw cap with polyethylene liner, containing 200 ml.
This is supplied as an original pack.

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 Limited
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Hitchin
Herts SG4 7QR
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 278/4/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 December 1980.

Date of last renewal: 1 December 2005.

10 DATE OF REVISION OF THE TEXT

February 2015