Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Psoriderm Scalp Lotion Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Distilled Coal Tar2.5% w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo
Golden-brown coloured foaming therapeutic shampoo.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of psoriasis of the scalp.

4.2 Posology and method of administration

Use as a shampoo, daily if necessary, reducing the frequency of use to once or twice a week as the condition improves. Thereafter, occasional use may be necessary.
For adults, children and the elderly: wet the hair thoroughly. Apply a small amount of the shampoo to the scalp (approximately a quantity the size of a two Euro piece for short hair, adjusting up depending on length/thickness of hair) and massage gently until a rich lather has been generated. Retain on the scalp for a few minutes. Remove excess lather with the hands before rinsing with warm water. If necessary, repeat the above procedure.

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

Keep away from the eyes and mucous membranes.
Replace cap after use.
Avoid spillage.
For external use only.
If there is no improvement after 4 weeks, or the scalp condition seems to look or feel worse, discontinue treatment and tell your doctor, pharmacist or nurse.

4.5 Interaction with other medicinal products and other forms of interactions

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 Scalp Lotion 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 Scalp Lotion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeuticgroup:Antipsoriatics for topical use, Tars. 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 Scalp Lotion 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

Not applicable.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lecithin
Trolamine laurilsulfate
Lauric acid diethanolamide
Disodium edetate
Sodium chloride
Phenoxyethanol
Ammonium sulfate
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

White, high density polyethylene bottle incorporating a low density polyethylene plug and polypropylene screw cap with internal spigot seal, containing 250 ml.

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
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/001/002

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

December 2020