

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Psoriderm Scalp Lotion Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Distilled coal tar 2.5% w/v

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

For adults, children and the elderly.

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.

Wet the hair thoroughly. Apply a small amount of the shampoo to the scalp (approximately a quantity the size of a fifty pence 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 hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Keep away from the eyes and mucous membranes.

Replace cap after use.

Avoid spillage.

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 Interactions 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 rare cases 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 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

There are no known toxic effects resulting from excessive use of Psoriderm Scalp Lotion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 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 scalp 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 Shampoo 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.

Lecithin is added to Psoriderm Scalp Lotion Shampoo to soften psoriasis scales and thereby enhance the absorption of the coal tar.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lecithin

Triethanolamine lauryl sulfate (trolamine lauril sulfate) (contains methylchloroisothiazolinone /methylisothiazolinone (3:1) as a preservative)

Lauric acid diethanolamide

Disodium edetate

Sodium chloride
Phenoxyethanol
Ammonium sulfate
Water purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months in unopened container

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

250 ml white, high density polyethylene BOTTLE incorporating a low density polyethylene plug. Polypropylene SCREW CAP with internal spigot seal.

6.6 Instruction for use, handling and disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited
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8. MARKETING AUTHORISATION NUMBER

PL 00173/5001R

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

04/01/2007

10 DATE OF REVISION OF THE TEXT

23/12/2024