

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Psoriderm Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Distilled Coal Tar 6.0% w/w

Excipients with known effect:

1g of cream contains 50 mg of propylene glycol (E 1520)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Smooth, buff-coloured cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of sub-acute and chronic psoriasis, including psoriasis of the scalp and flexures.

4.2 Posology and method of administration

For adults, children and the elderly: apply to the affected area once or twice daily, or as recommended by the physician. Wash hands after use.

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

Propylene glycol may cause skin irritation.

Keep away from the eyes and mucous membranes.

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.

Replace cap after use.

Avoid spillage.

For external use only.

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, although the excipient propylene glycol may on rare occasions cause skin irritation in sensitive people. In the rare event of skin irritation, acne-like eruptions or photosensitivity discontinue treatment. Rarely, Psoriderm Cream 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 Cream.

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 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 Cream 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
Stearic acid
Isopropyl palmitate
Propylene glycol (E 1520)
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 jar, with black bakelite screw cap incorporating a Steran liner, containing 225 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 (Ireland) Limited
38 Main Street
Swords
Co Dublin
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/001/001

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