

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

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

Keep away from the eyes, mucous membranes, genital or rectal areas. Avoid cuts and grazes or infected skin.

Propylene glycol may cause skin irritation.

Replace cap after use.

Avoid spillage.

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 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 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 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 Cream.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

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

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lecithin

Stearic acid

Isopropyl palmitate

Propylene glycol (E 1520)

Trolamine

Phenoxyethanol

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°

6.5 Nature and contents of container

225 ml amber glass JAR with black bakelite SCREWCAP incorporating a Steran liner. This is supplied as an original pack (OP).

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place, Gosmore

Hitchin, Herts, SG4 7QR, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 0173/5000R

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

24 November 1972 / 18 September 2000

10 DATE OF REVISION OF THE TEXT

27/01/2020