

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dermacreme Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide	8.0% w/w
Menthol	0.015% w/w
Methyl Salicylate	3.0% w/w
Liquefied Phenol	1.0% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cuts, grazes, minor burns and scalds.

4.2 Posology and method of administration

Adults (all ages) and Children – Apply directly to the affected parts.

4.3 Contraindications

Hypersensitivity to any of the ingredients

4.4 Special warnings and precautions for use

Consult your doctor if symptoms persist

Keep out of the reach of children

For external use only

Replace cap firmly after use

4.5 Interaction with other medicinal products

and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

The product is not contraindicated during pregnancy and lactation. However, as with all medicines during pregnancy, caution should be exercised.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Skin disorders

Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders

Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

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. By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

Repeated Topical Application

Frequently repeated topical application on the same site could theoretically lead to skin irritation. However, since the product is only intended for minor skin trauma, extensive exposure is unlikely.

Accidental or Deliberate Ingestion

The product would only be expected to be harmful if orally ingested in very large quantities. This is unlikely due to the unpleasant taste of the product. In such a case the primary concern would be the phenol intake which can cause nausea, vomiting, diarrhoea and headache.

Treatment

Gastric lavage with water and charcoal. Administration of demulcents such as egg white or milk and supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Menthol has analgesic and antipruritic actions. Methyl Salicylate relieves pain. Liquefied Phenol has bacteriostatic and local anaesthetic actions. Zinc Oxide has protective actions and is also a soothing and mild astringent.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dispersed Pink 11150/Erythrosine (E127)

Yellow Soft Paraffin
Starch
Lanolin Anhydrous
Hard Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Polyethylene jar with hard plastic screwcap: 30g.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

BELL SONS & COMPANY (DRUGGISTS) LIMITED
GIFFORD HOUSE
SLAIDBURN CRESCENT
SOUTHPORT
MERSEYSIDE
PR9 9AL
UNITED KINGDOM

8 MARKETING AUTHORISATION NUMBER(S)

PL 03105/0085

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

19th September 2007

10 DATE OF REVISION OF THE TEXT

25/09/2023