

For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

DERMOCALM LOTION

1. GENERIC NAME

Calamine and Light Liquid Paraffin Lotion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition
Calamine IP 8 .0 % w/w
Light Liquid Paraffin IP 10.0 % w/w
in a lotion base

3. DOSAGE FORM AND STRENGTH

Lotion.

Composition
Calamine IP 8 .0 % w/w
Light Liquid Paraffin IP 10.0 % w/w
in a lotion base

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

DERMOCALM LOTION is indicated for use as an anti-pruritic and soothing agent.

4.2 Posology and Method of Administration

Topical. Applied directly to the skin.

DERMOCALM LOTION is suitable for use by adults, children and the elderly.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 7 *list of excipients*.

4.4 Special Warnings and Precautions for Use

May mask x-ray pictures under certain circumstances.

The patient should be advised to use care to stop using the product and consult their doctor if a rash or skin irritation occurs.

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 Light Liquid Paraffin 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 Drug Interaction

None known.

4.6 Use in special Populations

Fertility

There are no data on the use of *DERMOCALM LOTION* on human fertility.

Pregnancy

There are no data on the use of *DERMOCALM LOTION* when used during pregnancy.

Lactation

There are no data on the use of *DERMOCALM LOTION* when used during lactation.

It is not known if *DERMOCALM LOTION* is excreted in human milk.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable Effects

Application site reactions including application site irritation, rash, erythema, pruritus.

Application site hypersensitivity reactions including application site dermatitis.

4.9 Overdose

Overdose is considered unlikely with *DERMOCALM LOTION* as the product is intended for cutaneous use only. In case of accidental ingestion, management should be as clinically indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action and Pharmacodynamic effects

Calamine

Calamine has a mild astringent action of the skin and is used as a dusting powder, cream, lotion or ointment in a variety of skin conditions.

Light Liquid Paraffin

Light liquid paraffin exerts an emollient effect by forming an occlusive film on the stratum corneum.

5.2 Pharmacokinetic Properties

No information available.

6. NONCLINICAL PROPERTIES

No data available.

7. DESCRIPTION

Lotion

Composition

Calamine IP	8.0 % w/w
Light Liquid Paraffin IP in a lotion base	10.0 % w/w

8. PHARMACEUTICAL PARTICULARS

List of excipients

Aloe Vera gel, Glycerin, Bentonite, Brij S2-SO-(TH) (Brij-72), Brij-S21-FL-(TH) (Brij-721), Dimethicone 350 (Silicone Oil 350), Dow corning 1403 fluid, Magnesium Aluminium Silicate, Perfume composition 12447, Citric Acid Monohydrate, Methyl paraben, Propyl paraben, Purified water

8.1 Incompatibilities

There are no relevant data available.

8.2 Shelf life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Bottle in a carton.

8.4 Storage and Handling Instruction

Store at a temperature not exceeding 30°C.

Do not freeze

Keep out of reach of children.

For external use only.

Shake well before use.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *DERMOCALM LOTION*. Patients (and/or patient's caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.

For further information please contact:

GlaxoSmithKline Pharmaceuticals Limited

Registered Office

Dr Annie Besant Road, Worli,
Mumbai 400030. India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

19-Oct-22

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Adapted from:

1. Calamine Lotion BP SmPC (last updated on emc: 21 Nov 2016).

Available at: <https://www.medicines.org.uk/emc/product/4822/>

2. Oilatum Emollient SmPC (last updated on emc: 20 Jun 2022).

Available at: <https://www.medicines.org.uk/emc/product/5454/>