

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calamine Lotion BP
Superdrug Calamine Lotion BP
Sainsbury's Healthcare Calamine Lotion
Tesco Health Calamine Lotion
Morrisons Calamine Lotion BP
Numark Health Calamine Lotion
Wilko Calamine Lotion
Almus Calamine Lotion
Boots Calamine Lotion
Relonchem Calamine Lotion BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine BP
Zinc Oxide BP

3. PHARMACEUTICAL FORM

Topical suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Use as a mild astringent, cooling lotion for minor skin irritations and sunburn.

4.2 Posology and method of administration

Topical. Applied directly to the skin.

Recommended dose and dosage schedule.

For children, adults and the elderly apply with cotton wool to the affected area as required.

4.3 Contraindications

Known hypersensitivity to any of the ingredients

4.4 Special warnings and precautions for use

Shake bottle well.

For external use only.

Do not use on broken skin.

Keep all medicines away from children.

4.5 Interaction with other medicinal products and other forms of interaction

May mask x-ray pictures under certain circumstances.

4.6 Pregnancy and lactation

No evidence has been found as to the safety of the product when used during pregnancy and lactation. However, the product has been used for many years without any apparent ill effects.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Occasional hypersensitivity or irritant reactions.

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

If accidentally ingested treat symptomatically.

Overdose is considered unlikely with this product. However, if large quantities have been ingested, vomiting, inflammation of mucous membranes of the mouth and stomach, weakness, mental confusion, cold sweats, depression of pulse and leg cramps may occur.

Where phenol has been swallowed it may be necessary to empty the stomach by aspiration and lavage.

Castor oil or olive oil may be added to the water to dissolve the phenol and delay absorption: 50ml of oil may be left in the stomach.

The patient should be kept warm and pulmonary oedema, systemic acidosis, respiratory failure and circulatory failure should be treated symptomatically. Respiration may have to be assisted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calamine has a mild astringent on the skin and is used to relieve the discomfort of dermatitis.

Calamine lotion cools the skin by evaporation and is useful for allaying the pain and swelling of sunburn.

Zinc oxide is applied externally as a mild astringent for the skin and protective application in eczema and as a protective for slight excoriations.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

None available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bentonite BP
Sodium Citrate BP
Liquefied Phenol BP
Glycerol BP
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months in unopened bottle.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

White or amber glass bottle with tamper evident screw cap.
100 ml, 150 ml, 200 ml, 500 ml.

6.6 Instructions for use/handling

Shake well before use

7. MARKETING AUTHORISATION HOLDER

Bell, Sons & Co (Druggists) Ltd
Gifford House
Slaidburn Crescent
Southport
Merseyside
PR9 9AL

8. MARKETING AUTHORISATION NUMBER

PL 03105/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/04/2009

10 DATE OF REVISION OF THE TEXT

12/11/2025