MAGZO
PHARMACEUTICAL & LABS LTD
ADDRESS:No 25, Crestfield Avenue, Peace Estate, Gama Kwari, Jaba,
Nassarawa LGA, Kano State
PHONE NO: 08066894569 E-MAIL: magzopharmaceutical@gmail.com

SUMMARY OF PRODUCT CHARACTERISTICS
CALAMINE LOTION

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SUMMARY OF PRODUCT CHARACTERISTICS CALAMINE LOTION

Summary of Product Characteristics

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9. Date of first authorisation/renewal of the authorisation
10. Date of revision of the text

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1. Name of the medicinal product
CALAMINE LOTION BP

2. Qualitative and quantitative composition

Label Claim:	
CALAMINE POWDER BP.	15% w/v
ZINC OXIDE BP.	5% w/v

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Lotion

4. Clinical particulars

4.1 Therapeutic indications
CALAMINE LOTION is indicated for the relief of mild sunburn and other minor skin conditions

4.2 Posology and method of administration
For Topical use. Applied directly to skin
Recommended dose and dosage schedule
The product is suitable for use by adults, children and the elderly.
Apply gently with a pad of cotton wool to the affected parts as required.

4.3 Contraindications

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Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use
Shake the bottle.
For external use only.
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 Fertility, 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.

4.9 Overdose

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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 action of the skin and is used as a dusting powder, cream, lotion or ointment in a variety of skin conditions.
Zinc oxide has a mildly antiseptic action and is a mild astringent, it has soothing and protective properties.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

None

6. Pharmaceutical particulars

6.1 List of excipients

CARBOXYL METHYL CELLULOSE
BENTONITE

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LIQUID PHENOL
NA CITRATE
GLYCERINE
PURIFIED WATER

6.2 Incompatibilities
None known

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container

Bottle:	Amber PET
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	100ml.

6.6 Special precautions for disposal and other handling
No special requirements.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.

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7. Marketing authorisation holder

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08066894569.

Maufacturer: Magzo Pharmaceutical & Labs Ltd, No.25, Crestfield Avenue, Peace Estate, Gama Kwari Jaba, Nassarawa LGA, Kano State

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Not Applicable