



# UGOLAB PRODUCTIONS (NIG.) LTD.

*MANUFACTURERS OF PHARMACEUTICAL PRODUCTS AND GENERAL MERCHANTS*

**Head office:** 31A Burma Road, Sabon Gari, Kano.

**Factory:** 157/159, Club Road, Bompai Ind. Layout, Kano.

**Tel:** +234 (80) 23094219

**Website:** [www.ugolab.com](http://www.ugolab.com)

**Email:** [ugolabpharm@yahoo.com](mailto:ugolabpharm@yahoo.com)

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## SUMMARY OF PRODUCT CHARACTERISTICS CALAMINE LOTION

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## SUMMARY OF PRODUCT CHARACTERISTICS CALAMINE LOTION

### 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

BABY COUGH 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**

Overdose is considered unlikely with this product. However, if large quantities have been ingested, vomiting, inflammation of mucous



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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**

BENTONITE

LIQUID PHENOL

NA CITRATE



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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 Glass
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.

## 7. Marketing authorisation holder



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UGOLAB PRODUCTIONS NIG. LTD  
157/159 CLUB ROAD, BOMPAI INDUS LAYOUT, KANO,  
KANO STATE.  
NIGERIA.

### **8. Marketing authorisation number(s)**

04-4727

### **9. Date of first authorisation/renewal of the authorisation**

31/08/23

### **10. Date of revision of the text**

Not Applicable

### **Company Contact Details**

UGOLAB PRODUCTIONS NIG. LTD

#### **Address**

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Kano State.

Nigeria

#### **Telephone**

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