



SUMMARY OF PRODUCT CHARACTERISTICS

ESOMA CALAMINE LOTION



1. Name of the medicinal Product

1.1 Name of the medicinal Product

Calamine , Zinc Oxide

1.2 Strength

Calamine 15%w/w

Zinc Oxide 5%w/w

1.3 Pharmaceutical Form

Topical Lotion

Pink Color lotion filled in PET bottle.

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Each 100ml of Esoma Calamine Lotion contains;

Calamine + Zinc Oxide + Sodium Citrate + Bentonite + Phenol + Glycerin.

2.2 Quantitative declaration

| S/N | INGREDIENT | SPECIFICATION | QUANTITY in 100ml | REASON for INCLUSION |
|-----|----------------|---------------|-------------------|--------------------------------------------|
| 1 | Calamine | BP | 15g | API (Counter irritant), Mild antiseptic |
| 2 | Zinc Oxide | BP | 5g | API (Mild antiseptic, Anti-inflammatory) |
| 3 | Sodium Citrate | BP | 0.5g | Chelating agent |
| 4 | Bentonite | BP | 3g | Healing properties; draws toxins from skin |
| 5 | Phenol | BP | 0.4226g | Disinfectant |
| 6 | Glycerin | BP | 6.39 | Moisturizing agent |



3. Pharmaceutical Form

Topical Lotion

Pink Color lotion filled in PET bottle.

4. Clinical Particulars

4.1 Therapeutic Indications

A skin protectant, indicated for the topical relief of symptoms of pain, redness, itching and discomfort caused by chicken pox, insect bites or stings, measles, sunburn or other minor skin irritations.

Dosage

Child and adult: One application 3 to 4 times daily in a thin layer.

4.2 Posology and Method of Administration

Shake bottle very well before use, Soak lotion on cotton wool and gently dab affected area. It works by counter irritant effect, after application to the skin the calamine evaporates producing a cooling effect and relief from itching. It leaves a thin film on drying. Discontinue use if irritation occurs or as directed by the physician.

Pediatric population

Appropriate studies on the relationship of age to the effects of calamine have not been performed in the pediatric population. However, no pediatrics-specific problems have been documented to date.

4.3 Contraindications

Esoma Calamine lotion has been contraindicated in persons with known hypersensitivity or allergy to any ingredient. It should not be used if you are allergic to one or any of its ingredients. Kindly inform your doctor or pharmacist if you have previously experienced such an allergy.

4.4 Special Warnings and Special Precautions for Use

Esoma Calamine lotion should be applied only to skin. It is necessary to wash hands after usage to avoid accidental entry of drug in eyes and mouth. Esoma calamine lotion is for EXTERNAL USE ONLY.

4.5 Interaction with other medicinal products and other forms of interaction

This medicine is not known to affect other medicines, however, if calamine lotion is applied just before or after applying other medications like creams, ointments, or lotions, they could potentially reduce the potency. For this reason, you should try to leave a few minutes between applying calamine and other medicated skin products, unless otherwise directed by your physician. May mask x-ray pictures under certain circumstances.



4.6 Fertility, Pregnancy and Lactation

Not to be ingestible.

4.7 Effects on ability To Drive and use Machines

None.

4.8 Undesirable Effects

Generally, calamine lotion is well tolerated, but can cause skin irritation in people hypersensitive to any of its ingredients.

4.9 Overdose

Overdose is considered unlikely with this product, however in cases of ingestion, 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 may be added to water to dissolve the phenol and delay absorption.

The patient should be kept warm. Pulmonary oedema, systemic acidosis, respiratory failure and circulatory failure should be treated symptomatically.

5. Pharmacological Properties

5.1 Pharmacodynamics 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 mild antiseptic action and is a mild astringent, it has covering, soothing and protective properties.

Phenol functions as a preservative in calamine lotion while the bentonite is used as a stabilizing and suspending agent.

5.2 Pharmacokinetic Properties

Calamine applied topically evaporates on drying and is not absorbed through the skin.

5.3 Preclinical Safety Data

No other relevant preclinical data is available.

6. Pharmaceutical Particulars



6.1 List of Excipients

Bentonite
Sodium Citrate
Glycerol
Phenol

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months unopened.

6.4 Special Precautions for Storage

Store in a light resistant container not less than 30°C.

6.5 Nature and Contents of Container

100ml: PET bottle with red 28mm metallic screw cap with tamper proof.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

Esoma Pharmaceutical Ltd
Plot 54 cadastral zone 07-05 Extension 2, kubwa, Abuja.
Tel: 08036786233
Email: esomapharmacy@gmail.com

7.2 Name and Address of manufacturing site(s)

Esoma Pharmaceutical Ltd
Plot 54 cadastral zone 07-05 Extension 2, kubwa, Abuja.
Tel: 08036786233
Email: esomapharmacy@gmail.com



7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

—

9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable