



**SUMMARY OF PRODUCT  
CHARACTERISTICS  
(SmPC)**

**Of**

**DE-SHALOM CALAMINE LOTION**

## **1. Name of the medicinal Product**

### **1.1 Name of the medicinal Product**

De-Shalom Calamine Lotion

### **1.2 Pharmaceutical Form**

Topical Lotion

## **2. Qualitative and Quantitative Composition**

Calamine	15% w/v
Zinc Oxide	5% w/v
Bentonite	3% w/v
Liquified phenol	0.5% v/v

For a full list of excipients, see section 6.1

## **3. Pharmaceutical Form**

Topical Lotion

## **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 or as directed by the Physician.

### **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**

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**

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. 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 ingested.

#### **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**

Sodium Citrate

Glycerol

### **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 NAFDAC requirements.

## **7. Marketing Authorization Holder /Manufacturer**

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