

## **PACKAGE INSERT TEMPLATE FOR CALAMINE & ZINC OXIDE CREAM/LOTION**

### **Brand or Product Name**

*[Product name] Cream*

*[Product name] Lotion*

### **Name and Strength of Active Substance(s)**

Calamine..... % w/w (w/v) [1-25%]

Zinc Oxide.... % w/w (w/v) [1-25%]

### **Product Description**

*[Visual description of the appearance of the product (eg colour, odour, viscosity, texture)]*

*eg Pinkish red coloured, smooth suspension with strong menthol smell*

*A pink homogeneous cream*

*Smooth pink cream with a pleasant rose odour*

### **Pharmacodynamics**

Calamine has mild astringent and antipruritic actions on the skin and is used to relieve the discomfort of dermatitis as it produces a cooling effect and helps to divert attention away from the itching and thus giving relief from skin irritations.

Zinc oxide is applied externally as a mild astringent for the skin

Zinc oxide has soothing and protective properties and is used in topical preparations for eczema, slight excoriations, wounds and haemorrhoids. It also reflects ultraviolet radiation and can be used as a physical sunscreen.

### **Pharmacokinetics**

*Absorption*

Calamine and Zinc Oxide are not absorbed through the skin

### **Indication**

Indicated for the topical soothing relief of itching, pain, and discomfort due to minor skin irritations, such as those caused by eczemas, insect bites, insect stings, prickly heat, sunburn, napkin rash , cosmetic rashes, pruritis of dry skin including as well as symptomatic relief of itchiness in Chickenpox viral infection.

*Updated August 2011*

## **Recommended Dosage**

Wash and dry affected area before each application

Apply sparingly to the affected parts and surrounding skin areas twice or three times daily.

Repeated applications may be administered as needed

\*\*Lotion: Shake well before use. Lotion should be applied with a cotton ball/pledget moistened with the lotion. Then the medication should be allowed to dry on the skin.

\*\*Extremes of temperature, wearing tight fitting nappies or non-breathable clothing such as polyester or nylon can make itching worse.

## **Mode of Administration**

Topical

## **Contraindications**

Hypersensitivity to any ingredients/components in the formulation

## **Warnings and Precautions**

For external use

Not to be taken.

Avoid contacts with the eyes and other mucous membranes such as mouth, nose and genital region.

Not to be applied to abraded, blistered, inflamed, raw or oozing areas of the skin.

Do not use on open wounds or burns

Discontinue use if rash, irritation, burning sensation or sensitivity develops/occurs.

If symptoms persist, consult your pharmacist or doctor

### *Effects on Ability to Drive and Use Machines*

Unlikely to impair a patient's ability to drive or use machinery

## **Interactions with Other Medicaments**

No clinically significant interactions known.

*Updated August 2011*

## **Statement on Usage During Pregnancy and Lactation**

The safety of calamine and zinc oxide during pregnancy and lactation has not been established but use during these periods is not considered to constitute a hazard.

## **Adverse Effects / Undesirable Effects**

Calamine and zinc oxide is well-tolerated except for occasional dryness following and excessive use.

Occasional hypersensitivity reactions such as itchiness in sensitive individuals

## **Overdose and Treatment**

Overdose arising from the topical application is extremely remote. As the ingredients are inert and very poorly absorbed, effects if any arising from accidental overdose (orally) is unlikely to be life threatening.

If ingested symptoms of overdose include gastritis, nausea, vomiting, epigastric discomfort and diarrhoea.

Treatment consists of symptomatic measures only

Maintain adequate hydration if vomiting or diarrhea becomes extensive.

Milk or antacids may be used to allay gastritis in the event of oral ingestion

## **Storage Conditions**

*[ eg Store below .....°C ]*

## **Dosage Forms and Packaging Available**

*[Packaging type & pack size]*

Pack size: Liquid – max 250ml

Others – 60g

## **Name and Address of Manufacturer**

*[Name & full address of manufacturer ]*

## **Name and Address of Marketing Authorization Holder**

*[Name & full address of marketing authorization holder ]*

## **Date of Revision of Package Insert**

*[ day/month/year ]*

*Updated August 2011*