

## **1. NAME OF THE MEDICINAL PRODUCT**

Galways Calamine Lotion BP

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

100ml of Galways Calamine lotion contains:

### Active ingredients

Calamine BP	15.0g
Zinc Oxide Ph Eur	5.0g

For a full list of excipients, see section 6.1

## **3. PHARMACEUTICAL FORM**

Lotion

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

For the relief of minor skin rashes and irritation.

### **4.2 Posology and method of administration**

#### Posology

#### Adults, children and elderly:

To be applied when required to the affected area.

#### Method of administration

For topical application.

### **4.3 Contraindications**

Hypersensitivity to any of the ingredients.

### **4.4 Special warnings and precautions for use**

For external use only.

Shake the bottle before use.

Keep all medicines out of the reach of children.

### **4.5 Interaction with other medicinal products and other forms of interaction**

No clinically significant interactions known.

May mask x-ray pictures under certain circumstances.

### **4.6 Pregnancy and Lactation**

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

#### **4.7 Effects on ability to drive and use machines**

No adverse effects known.

#### **4.8 Undesirable effects**

Occasional hypersensitivity or irritant reactions.

#### **4.9 Overdose**

If ingested symptoms of overdosage include anorexia, nausea, vomiting, epigastric discomfort and diarrhoea. Treatment consists of symptomatic measures only.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamics properties:**

Pharmacotherapeutic group: Antipruritic (topical), ATC code: D02AB

Calamine has a mild astringent action on the skin.

#### **5.2 Pharmacokinetic properties**

None known.

#### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber which are additional to that already included.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Liquified Phenol

Bentonite

Sodium Citrate

Glycerol

Deionised Water

#### **6.2 Incompatibilities**

None stated.

#### **6.3 Shelf life**

36 months unopened.

#### **6.4 Special precautions for storage**

Store below 30°C.

#### **6.5 Nature and contents of container <and special equipment for use, administration or implantation>**

A white flint pet bottle with an Aluminium screw cap.

Pack sizes: 100 millilitres

#### **6.6 Special precautions for disposal <and other handling>**

None stated.

### **7. APPLICANT/MANUFACTURER**

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