

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Calamine Lotion BP

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine 15% w/v and Zinc Oxide 5% w/v.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous suspension  
Pink cutaneous suspension.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Calamine lotion has mild astringent and soothing properties. It is indicated for the management of minor pruritic conditions.

##### 4.2 Posology and method of administration

For topical use. Shake bottle before use.  
Apply to affected area three times daily as required.

##### 4.3 Contraindications

None.

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

This product is for external use only.  
If symptoms persist or worsen consult your doctor.

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

None.

##### 4.6 Pregnancy and lactation

Safety in pregnancy has not been established.

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

None known.

#### **4.8 Undesirable effects**

None known.

#### **4.9 Overdose**

Not Applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Calamine Lotion acts locally on the skin and has mild astringent and soothing properties.

#### **5.2 Pharmacokinetic properties**

No information available.

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

Calamine and Zinc Oxide are well established drug substances and have been widely used for many years.

### **6 PHARMACEUTICAL PARTICULARS**

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

Bentonite  
Sodium Citrate  
Phenol  
Glycerol  
Purified Water

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf Life**

2 years.

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

Do not store above 25°C.

#### **6.5 Nature and contents of container**

Amber Type III soda glass bottles with LDPE liner, unlined PP or PP screw caps with a wood pulp wadding and aluminium foil contact layer containing 125ml, 250 ml or 500 ml of suspension.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Shake bottle before use.

**7 MARKETING AUTHORISATION HOLDER**

RiceSteele Manufacturing Limited  
Cookstown Industrial Estate  
Tallaght  
Dublin 24

**8 MARKETING AUTHORISATION NUMBER**

PA 95/21/1

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 27 April 1993

Date of last renewal: 27 April 2003

**10 DATE OF REVISION OF THE TEXT**

April 2003