

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lanacane 3 % <sup>w</sup>/<sub>w</sub> Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of cream contains 30mg benzocaine (3%w/w).

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cream

A smooth, off-white cream having a rose-like fragrance.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Lanacane Cream is recommended for the relief of skin and membrane itching and irritation. It functions as a topical anaesthetic for conditions such as heat rash, itching and irritation of dry skin aggravated by scratching, everyday scrapes, cuts and skin chafe, insect bites, nettle rash, chapping, external vaginal and rectal itching.

### 4.2 Posology and method of administration

For topical administration.

Recommended dosage: Application to the affected area three or four times daily.

Not suitable for children under twelve years of age.

### 4.3 Contraindications

May possibly cause sensitivity. If this occurs, treatment should be stopped and medical advice sought.

### 4.4 Special warnings and precautions for use

Not for use on extensive body areas or on the eyes. If symptoms persist for more than one week, or worsen, discontinue use and consult your doctor. Not suitable for children under twelve years of age. As with all medicines, keep out of reach of children. Do not use in pregnancy without first consulting a doctor. For external use only.

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

None known.

### 4.6 Fertility, pregnancy and lactation

Do not use in pregnancy without first consulting a doctor.

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

None.

## 4.8 Undesirable effects

May possibly cause sensitivity. If this occurs, treatment should be stopped and medical advice sought.

## 4.9 Overdose

Not applicable.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

### Benzocaine

Benzocaine is a surface anaesthetic of the ester type.

## 5.2 Pharmacokinetic properties

Benzocaine has a low systemic toxicity.

## 5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Stearic acid  
Glycerol monostearate  
Glycerol (glycerin 96%)  
Trolamine (triethanolamine)  
Zinc oxide  
Sulphonated castor oil  
Isopropyl alcoholChlorothymol  
Perfume Lano Rose C  
Docusate sodium  
Diethylene glycol monoethyl ether  
Purified water

## 6.2 Incompatibilities

None known.

## 6.3 Shelf life

5 years.

## **6.4 Special precautions for storage**

Do not store above 25°C.

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

Aluminium tube with a membrane covered nozzle and white high density polyethylene cap.  
Pack sizes: 30g and 60g.

## **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**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Ireland Limited  
7 Riverwalk  
Citywest Business Campus  
Dublin 24  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA 0979/063/001

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

Date of first authorisation: 21 June 1976

Date of last renewal: 21 June 2006

## **10 DATE OF REVISION OF THE TEXT**

June 2012