SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lanacane Creme

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	%	Specification
Benzocaine	3.0	E.P.

Excipients with known effect:

Fragrances containing allergens (citronellol, benzyl benzoate, geraniol, benzyl alcohol, citral, cinnamal, alcohol, linalool and d-limonene)	0.064% w/w
Sulphonated castor oil	2.015% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion creme in an aluminium tube.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For symptomatic relief of minor pain, itching, and irritation in the following localised skin conditions, such as insect bites, nettle stings, minor skin abrasions, and external genital and external anal itching.

4.2 Posology and method of administration

For short term use only. If pain persists for more than 7 days, or worsens, seek medical advice.

Posology

For adults, the elderly and children aged 12 years and over:

Apply a small amount to the affected area up to 3 times a day.

Children under 12 years: The safety and efficacy of Lanacane Creme in children aged less than 12 years have not been established. No data are available.

Method of administration

For topical administration.

4.3 Contraindications

Hypersensitivity to benzocaine or to any of the excipients listed in section 6.1 or paraaminobenzoic acid (PABA), parabens or paraphenylenediamine or to commercial hair dyes as there is cross-sensitivity between these products.

A history of allergy to local anaesthetics such as procaine, butacaine or any other 'caine' anaesthetics.

In patients who have a history of or are suspected to have, methaemoglobinaemia (see section 4.8). Do not use in patients who have a history of, or are suspected to have methaemoglobinaemia. The risk of methaemoglobinaemia is increased in patients who have a reduced haematological capacity for oxygen transport including those with glucose-6-phosphate dehydrogenase (G6PD) deficiency, haemaglobinopathies, or anaemia.

Do not use with sulphonamides (see section 4.5).

Do not use with cholinesterase inhibitors or in patients with reduced cholinesterase activity (see section 4.5).

Do not apply to large areas of skin, eczematous, sunburnt, infected or broken skin.

Do not use with occlusive dressings.

4.4 Special warnings and precautions for use

Local anaesthetics should not be used in patients with complete heart block.

Not for use on extensive body area or on the mouth or eyes or under conditions in which significant inhalation is likely.

This medicine contains fragrance with citronellol, benzyl benzoate, geraniol, benzyl alcohol, citral, cinnamal, alcohol, linalool and d-limonene that may cause allergic reactions.

Benzyl benzoate and benzyl alcohol may cause local irritation.

Lanacane contains sulphonated castor oil which may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Sulphonamides: Benzocaine is metabolised to para-aminobenzoic acid and may antagonise the effects of sulphonamides.

Cholinesterase Inhibitors: Cholinesterase inhibitors inhibit the metabolism of benzocaine.

4.6 Fertility, pregnancy and lactation

Do not use in pregnancy or during breast feeding without first consulting a doctor.

Pregnancy
There are no or a limited amounts of data from the use of benzocaine in pregnant women. Do not use in pregnancy without first consulting a doctor. As a precautionary measure, it is preferable to avoid the use of Lanacane during pregnancy.

Breast-feeding
There is insufficient information on the excretion of benzocaine/ metabolites in human milk. A risk to new-borns/infants cannot be excluded. The product should not be used during breast-feeding without first consulting a healthcare professional.

Fertility
No data on human fertility are available.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse events which have been associated with benzocaine are given below, listed by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥1/100 and <1/10), uncommon (≥ 1/1000 and <1/100), rare (≥ 1/10,000 and <1/1000), very rare (< 1/10,000) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Event
Blood and Lymphatic System Disorders	Not known	Methaemoglobinaemia

Immune System Disorders	Not known	Hypersensitivity reactions
Skin and Subcutaneous Tissue Disorders	Not known	Dermatitis allergic

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Symptoms
Overdose is more likely when the product is used on large areas of skin, on broken skin or when used with occlusive dressings.

The systemic toxicity of local anaesthetics such as benzocaine mainly involves the CNS and the cardiovascular system. Overdose may be associated with symptoms of methaemoglobinaemia which in mild cases may be asymptomatic or be associated with mild cyanosis. Symptoms of acute methaemoglobinaemia may include dyspnoea, headache, malaise, giddiness, and altered mental state.

Management
In the unlikely case of over dosage, treatment should be symptomatic and supportive. If symptoms to not improve, consult a healthcare professional.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antipruritics, incl. Antihistamines, Anesthetics, etc**;**

ATC Code: D04 AB04

Benzocaine applied to the skin acts as a topical local anaesthetic, acting on nerve endings and receptors, temporarily reducing the itching and minor pain associated with various thermal, mechanical or chemical stimuli. The vanishing creme base also helps soothe, lubricate, and protect irritated skin.

5.2 Pharmacokinetic properties

When used as directed, some benzocaine applied topically may be absorbed through the skin and mucous membranes and is hydrolysed by esterases in the

plasma and in the liver, but this should be of negligible consequence. Benzocaine has the quickest onset and shortest duration of action of the commonly used topical anaesthetics.

5.3 Preclinical safety data

None

6.1 List of excipients

Chlorothymol, diethylene glycol monoethyl ether, docusate sodium, fragrance (contains citronellol, benzyl benzoate, geraniol, benzyl alcohol, citral, cinnamal, alcohol, linalool and d-limonene), glycerine, glycerol monostearate, isopropyl alcohol, stearic acid, sulfonated castor oil, triethanolamine, water, zinc oxide.

6.2 Incompatibilities

None known.

6.3 Shelf life

Five years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

In 30 gram and 60 gram aluminium tubes with a membrane covered nozzle and white high density polyethylene cap, overpacked in a printed folding cardboard unit carton

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd, 103-105 Bath Road, Slough, Berkshire, SL1 3UH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0671

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th April 1990 / 23rd July 1996

10 DATE OF REVISION OF THE TEXT

17/12/2025