

**SUMMARY OF PRODUCT CHARACTERISTICS  
(SmPC)**

**For**

**ROBERTS ANTISEPTIC LIQUID  
(LIME FRESH )**

**COMPANY : PZ CUSSENS NIG PLC**

# SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

## 1. NAME OF MEDICINAL PRODUCT

Roberts Antiseptic Liquid - Lime Fresh

NAFDAC NUMBER: A4-9097

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

S/N	INGREDIENT	% W/W
1	Deionised Water - Purified	71.588002
2	Ethanol	9.400
3	<b>Castor Soap</b>	
	Ricinus Communis (Castor) Seed Oil	6.038
	Sodium Hydroxide - 47% w/w Solution	1.600
4	Di-chloro-m-xlenol	2.000
5	Pine oil	8.500
6	Fragrance	0.810
7	Benzotriazolyl Dodecyl p-Cresol	0.063
8	Colour Yellow (CI 47005)	0.000749
9	Colour Blue (CI 47180)	0.000249
	<b>Total</b>	<b>100.00</b>

## 3. PHARMACEUTICAL FORM

1	Appearance	Clear Light Green
2	Odour	Characteristic of Lime
3	pH @ 25°C	9.0 – 10.0
4	Active (DCMX)	2.0

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Not Applicable

### 4.2 Posology and Method of Administration

Not Applicable as the product is for external use only.

### 4.3 Contraindications

No report of any hypersensitivity to this product

### 4.4 Special warnings and precautions for use

Do not swallow. Keep out of reach of children.

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

No interaction studies have been performed.

#### **4.6 Pregnancy and Lactation**

No record of any.

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

Not relevant.

#### **4.8 Undesirable effects**

No record of any.

#### **4.9 Overdose**

No case of overdose has been reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamics**

Mechanism of action: the product denatures microbial cell wall and membrane thereby causing microbial cytolysis.

#### **5.2 Pharmacokinetic properties**

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

### **6. PHARMACEUTICAL PARTICULARS**

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

No excipient

#### **6.2 Incompatibilities**

Not applicable

#### **6.3 Shelf Life**

3 years

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

Store below 30°C

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

PET bottle and PP cap in the following pack sizes 125ml, 250ml, 500ml, 1Litre

#### **6.6 Special precautions for disposal**

No special requirements

### **7. Applicants/Manufacturer**

PZ Cussons Nigeria PLC

45/47 Town Planning Way, Ilupeju Industrial Estate

P.M.B. 21132, Ikeja, Lagos.

Tel 01-7000180