

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

For

**ROBERTS ANTISEPTIC LIQUID
(ORIGINAL)**

COMPANY : PZ CUSONS NIG PLC

1. NAME OF MEDICINAL PRODUCT

Roberts Antiseptic Liquid - Original

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

S/N	INGREDIENT	% W/W
1	Deionised Water - Purified	72.4387
2	Ethanol	9.4000
3	Castor Soap	
	Ricinus Communis (Castor) Seed Oil	6.0380
	Sodium Hydroxide - 47% w/w Solution	1.6000
4	Di-chloro-m-xlenol	2.0000
5	Pine oil	8.5000
6	Burnt Caramel	0.0225
7	Liquitint Orange	0.0008
	Total	100.00

3. PHARMACEUTICAL FORM

1	Appearance	Clear Light Brown
2	Odour	Characteristic of Pine
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

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