

**SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)**

For

**CUSSONS CAREX ANTISEPTIC LIQUID
(LIME FRESH)**

COMPANY : PZ CUSSONS NIG PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF MEDICINAL PRODUCT

Cussons Carex Antiseptic Liquid - Lime Fresh

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

S/N	INGREDIENT	% W/W
1	Deionised Water - Purified	69.998002
2	Ethanol	9.400
3	Castor Soap	
	Ricinus Communis (Castor) Seed Oil	6.038
	Sodium Hydroxide - 47% w/w Solution	1.600
4	Para-chloro-m-xyleneol	3.500
5	Pine oil	8.500
6	Fragrance	0.900
7	Benzotriazolyl Dodecyl p-Cresol	0.063
8	Colour Yellow (CI 47005)	0.000749
9	Colour Blue (CI 47180)	0.000249
	Total	100.00

3. PHARMACEUTICAL FORM

1	Appearance	Clear Light Green
2	Odour	Characteristic of Lime
3	pH @ 25°C	9.0 – 10.0
4	Active (PCMX)	3.5

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

First Aid: Included in first aid kits to clean and disinfect wounds during emergencies
 Hygiene: For cleaning and maintaining hygiene on hands, surfaces, medical devices, and health care environments to reduce microbial contamination and prevent infections.
 Helps prevent infection by killing or inhibiting microorganism in cuts, abrasions, lacerations, and burns.
 Spot & Pimples: Used topically to reduce acne-causing bacteria.

4.2 Posology and Method of Administration

For external use only.

Bathing: Add 2-3 capfuls to bath water

First Aid: Add 1 capful to 284ml of warm water.

Spots and Pimples: Add 1 capful to 284ml of warm water.

Floors/Surface: Add 2 capfuls to 4.5Ltr of water

4.3 Contraindications

Allergy or Sensitivity: Persons with known hypersensitivity to Para-chloro-m-xyleneol should avoid usage.

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

Limited data are available on its safety during pregnancy and breastfeeding, medical advice should be sought in these conditions.

4.7 Effects on ability to drive and use machines.

Not relevant.

4.8 Undesirable effects

No record of any.

4.9 Overdose

Not applicable as this product is for external use only.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics

Mechanism of action: The active ingredient works by disrupting the cell walls of bacteria, leading to leakage of cellular contents and cell death. It also interferes with enzyme systems essential for microbial metabolism.

Antimicrobial Spectrum: Its effective against broad range of Gram-positive and Gram-negative bacteria (which include *E. coli*, *S. aureus*, *S. epidermidis*, *P. aeruginosa*, etc). It also demonstrates antifungal and antiviral activity, although its efficacy varies by pathogen.

5.2 Pharmacokinetic properties

Absorption: Minimal systemic absorption when used topically, as PCMX acts primarily at the application site.

Distribution: Remains localised to the skin or mucosal surface where applied.

Mechanism of Excretion: If absorbed, it undergoes hepatic metabolism and is excreted in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water: Used as primary solvent and base for the liquid formulation

Ethanol: Enhance antimicrobial activity and improve solubility

Castor soap: soap of castor oil is a surfactant which aid in the dispersion and emulsification of PCMX, ensuring uniform application.

Benzotriazolyl Dodecyl p-Cresol: UV blocker which protects degradation of the product from ultraviolet rays.

Pine and Fragrance: Enhances the user experience.

Colours: provides an appealing appearance to liquid

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

Liquid: Dilute with large volume of water before disposal.

Container: Empty containers should be rinsed thoroughly before recycling or disposal.

7. Applicants/Manufacturer

PZ Cussons Nigeria PLC

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