SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

For

CUSSONS CAREX ANTISEPTIC LIQUID (ORIGINAL)

COMPANY: PZ CUSSONS NIG PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF MEDICINAL PRODUCT

Carex Antiseptic Liquid - Original

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

S/N	INGREDIENT	% W/W
1	Deionised Water - Purified	70.9387
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-xylenol	4.000
5	Pine oil	8.500
6	Burnt Caramel	0.0225
7	Liquitint Orange (Colour)	0.0008
	Total	**100.00**

3. PHARMACEUTICAL FORM

1	Appearance	Clear Light Brown
2	Odour	Characteristic of Pine
3	pH @ 25^{o}C	9.0 – 10.0
4	Active (PCMX)	4.0

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Medical - for cuts, bites, abrasions and insect stings.
Personal hygiene - for douching, dandruff; and spots and pimples.

4.2 Posology and Method of Administration

(a) Medical uses

For cuts, bites, abrasions and insect stings: wash the area with one tablespoonful of Dettol diluted in a half pint of water and cover with dry gauze or lint.

(b) Personal hygiene

For douching (when medically advised): two teaspoonfuls of Dettol diluted in two pints of warm water.

For dandruff: one tablespoonful of Dettol diluted in one pint of warm water. Saturate hair and scalp for 10 minutes, then shampoo.

For spots and pimples: bathe the affected area daily with one tablespoonful of Dettol diluted in half a pint of warm water (not for eczematous conditions).

Method of Administration
For external use only.
Always dilute the product before use.

4.3 Contraindications
Hypersensitivity to chloroxylenol or to any of the excipients listed in section 6.1.
Do not use on eczematous conditions

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

4.3 Special warnings and precautions for use
For external use only.
Not for use around eyes, ear, nose or mouth. If contact is made, wash thoroughly with cold water.
Not for use on large areas of the body or on sensitive skin.
If swallowed, wash out mouth and drink plenty of water or milk. If contact is made with eyes, wash thoroughly with cold water. In both cases consult your doctor.
Keep out of the sight and reach of children.
This medicine contains trace amounts of benzyl alcohol.
Benzyl alcohol may cause allergic reactions and mild local irritation.
This medicine contains fragrance with d-limonene.
d-Limonene may cause allergic reactions.

4.4 Interaction with other medicinal products and other forms of interaction
Not applicable.

No interaction studies have been performed.

4.5 Pregnancy and Lactation
No effects during pregnancy are anticipated, since systemic exposure from topical chloroxylenol use is negligible. Chloroxylenol can be used during pregnancy.

Breast-feeding
It is unknown whether chloroxylenol or its metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Application of the product to the breast is not recommended during breast feeding.

Fertility
No data on human fertility are available

4.6 Effects on ability to drive and use machines.
Not applicable

4.7 Undesirable effects

.
Adverse events which have been associated with chloroxylenol are given below, tabulated by system organ class and frequency. Frequencies are defines 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); 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 Events
Immune System Disorders	Not known	Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Not known	Skin sensitisation, dermatitis contact[1], skin discolouration, application site burn

Description of Selected Adverse Reactions
[1] Contact dermatitis can be associated with pruritus, erythema, skin scaling, itching and stinging.
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

4.8 Overdose

Symptoms

Topical application of undiluted chloroxylenol can cause skin burning. Symptoms reported include corrosion of the oral mucosa, larynx, and the gastrointestinal tract, bradycardia, hypotension, and renal failure. Large amounts may cause CNS depression. Pulmonary aspiration of chloroxylenol-based disinfectants may result in pneumonia, acute respiratory distress syndrome, and cardiorespiratory arrest. There have been reports of death by excessive consumption.

Oral ingestion may result in pharyngeal erosion, laryngeal oedema, stomatitis, bradycardia, hypotension, renal failure and CNS depression. Pulmonary aspiration following ingestion may result in pneumonia, acute respiratory distress syndrome and cardiorespiratory arrest. There have been reports of death by excessive consumption.

Management

In the case of ingestion or excess exposure, seek medical advice immediately. Careful observation of airway patency for 24-48 hours should be made post- ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Dermatologicals; Antiseptics and disinfectants; Phenol and derivatives; Chloroxylenol; **ATC Code**: D08AE05.

Chloroxylenol is a substituted phenol which has been widely used for many years as an ingredient of antiseptic/disinfectant products intended for external use. It is known to be bactericidal in low concentration to a wide range of Gram positive and Gram negative bacteria.

5.2 Pharmacokinetic properties

Chloroxylenol is well-absorbed when applied to the skin. It is extensively metabolised in the body, probably by the liver, and rapidly excreted, mainly in the urine, as sulphate and glucuronide conjugates.

Chloroxylenol has a low systemic toxicity, even at dosage levels many times higher than those likely to be absorbed during normal usage of carex Liquid.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

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.
Pine Oil: 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^{o}C

6.5 Nature and contents of container

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

6.6 Special precautions for disposal

For external use only

7. Applicants/Manufacturer

PZ Cussons Nigeria PLC
45/47 Town Planning Way, Ilupeju Industrial Estate
P.M.B. 21132, Ikeja, Lagos.
Tel 01-7000180