

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Dr Woodworth Citrus Splash 5%w/v Cutaneous Solution

1.1 Strength

Each 100ml contains Chloroxylonol 5000mg

1.2 Pharmaceutical/Dosage Form

Cutaneous Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

Active Substances

Chloroxylonol

Excipients

Terpineol, Castor Oil, Potassium Hydroxide, Oleic Acid, Rectified Spirit, Lemon Grass Oil, Caramel Colour and Purified Water

2.2 Quantitative Declaration

Chloroxylonol5000mg (5%w/v) per 100ml

Ingredients	Specification	Reason for Inclusion	Quantity per 100ml
Chloroxylonol	BP	Active Ingredient	5000mg
Terpineol	BP	Antibacterial & Antifungal	1ml
Castor Oil	BP	Emollient	630mg
Potassium Hydroxide	BP	Alkalizing agent	136mg
Oleic Acid	BP	Skin penetrant	0.75ml
Rectified Spirit	BP	Solvent	20ml
Lemon Grass Oil	BP	Fragrance Enhancer	1.25ml
Caramel Colour	BP	Colouring Agent	25mg
Purified Water	BP	Vehicle	Q.s to 100ml

For the full list of excipients, see section 6.1

3. PHARMACOLOGICAL CLASS

Cutaneous Solution

Clear, brownish homogenous solution at room temperature.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Dr Woodworth Citrus Splash has built in protection against germs. It cleans and freshens and has a non-bleaching action.

Dr Woodworth Citrus Splash has antiseptic and disinfectant properties.

4.2 Posology/Dosage and Method of Administration

Posology/Dosage

External preparation

Use as shown below. One capful =35ml

- Bathing /Skin Hygiene: Add 1 capful in bath water. Protection for the family against germs.
- Spot and Pimple Treatment: 1 capful to 500ml of warm water. Bathe affected area daily.
- First Aid (Cuts, Bites, Abrasions, Stings): 1 capful to 500ml of warm water. Wash affected area and cover with dry gauze or lint.
- Cleaning, Disinfecting and General Hygiene:
 - ~ Surfaces/Floors: 1 capful to 1 Litre of water
 - ~ Sinks/Toilets/Drains: 2 capfuls undiluted.

Special Populations

Paediatric Patients: Should not be used on children under 12 months of age for Chloroxylenol can cause irritation on their sensitive skin.

Method of Administration

For external use only

Topical Administration

4.3 Contraindications

Known hypersensitivity to the Chloroxylenol or any of the excipients mentioned in Section 6.1

Not to be used with patients who have Eczematous conditions.

Not to be used on children under 12 months of age

4.4 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 Terpineol (which is obtained from Pine Oil) that many have trace amounts of:

- Benzyl alcohol which may cause allergic reactions and mild local irritation.
- Fragrance with d-limonene which may cause allergic reactions.

4.5 Interactions with Other Drug Products and Other Forms of Interaction

No specific drug interaction studies have been undertaken; therefore the use of Chloroxylenol with any other topical products is not recommended.

4.6 Fertility, Pregnancy and Lactation

Fertility

No data on human fertility are available.

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure from topical chloroxylenol use is insignificant. Chloroxylenol can be used during pregnancy under medical supervision.

Lactation

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 lactation.

4.7 Effects on Ability to Drive and Use Machines

Does not have influence on the ability to drive and use machines.

4.8 Undesirable Effects

Adverse drug reactions are very rare (<1/10,000) following the topical use of Dr Woodworth Citrus Splash.

<i>System Organ Class</i>	<i>Frequency</i>	<i>Adverse Events</i>
Immune System Disorders	Very rare	Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Very rare	Skin sensitisation, dermatitis contact ¹ , skin discolouration, application site burn, and skin exfoliation

Description of Selected Adverse Reactions

¹ Contact dermatitis can be associated with pruritus, erythema, skin scaling, itching and stinging.

4.9 Overdose

Symptoms

Overdose is unlikely when used as directed since the Dr Woodworth Citrus Splash will run off the skin surface if an excessive amount is applied. Chloroxylenol has a low systemic toxicity, when used as instructed.

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 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 t_{max} of ~30 to 60 minutes and a half life ~50 to 60 minutes.

The clearance of Chloroxylenol is ~6 hours with no Chloroxylenol being detected in tissue after 24 hours. Chloroxylenol has a low systemic toxicity, even at dosage levels many times higher than those likely to be absorbed during normal usage of Dr Woodworth Citrus Splash.

5.3 Preclinical Safety Data

Preclinical studies with Chloroxylenol, although limited, do not indicate a risk of genotoxicity, carcinogenicity or teratogenicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Chloroxylenol
- Terpineol
- Castor Oil
- Potassium Hydroxide
- Oleic Acid
- Rectified Spirit

- Lemon Grass Oil
- Caramel Colour
- Purified Water

6.2 Incompatibilities

Not Applicable. However, Dr Woodworth should not be mixed with other medicinal products.

6.3 Shelf Life

3 years (36 months)

6.4 Special Precautions for Storage

Store in a cool dry place below 30°C

6.5 Nature and Contents of Container

Dr Woodworth Citrus Splash is filled into 220ml clear plastic bottles.

6.6 Special Precautions for Disposal of a Used Medicinal Product or Waste Materials derived from such Medicinal Product and Other Handling of the Product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Applicant

Name: ASPEN PHARMACARE NIGERIA LTD

Address: AGOS Business Lounge

54B Adeniyi Jones Avenue

Ikeja Lagos State

Country: NIGERIA

8. DRUG PRODUCT MANUFACTURER

Name: BETA HEALTHCARE INTERNATIONAL LTD

Address: Plot No. LR 209/6554, Mogadishu Road, Off Lung Lunga, Industrial Area, Nairobi

P.O. BOX 42569-00100 GPO Nairobi

Country: KENYA

Telephone: +254 20 2652042/89

E-Mail: info@ke.betashelys.com

7. NAFDAC REGISTRATION NUMBER(S)

B4-7187