

1. NAME OF THE MEDICINAL PRODUCT

Corysan Antiseptic Disinfectant (liquid) 250ml and 500ml HDPE plastic bottle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Corysan Antiseptic Disinfectant contains 4.8%w/v Chloroxylenol BPC .

Excipient

Caramel colour.

Isopropyl alcohol

Pine oil

Castor oil

3. PHARMACEUTICAL FORM

Corysan Antiseptic Disinfectant liquid 4.8%w/v Chloroxylenol.

Product description: Brownish liquid with characteristic pine odour which blooms when dropped in water.

4. Clinical particulars

4.1 Therapeutic indications

Medical - For cuts, bites, abrasions and insect stings (generally for first aid).

Personal hygiene - For dandruff; and spots and pimples

Non-therapeutic use: Bathing, Domestic cleaning and Laundry

4.2 Posology and method of administration

Posology

Adults:

For cuts, bites, abrasions and insect stings: Wash the affected area with product at 1 in 20 dilution (13.5 mL product in 270ml water).

For Bathing: 13.5 mL product in 2.70litres of water (1:200)

For Domestic Cleaning: 13.5 mL product in 270ml of water (1:20)

For Laundry: 13.5 mL product in 540ml of water (1:40)

PAEDIATRIC POPULATION

Children over the age of 1 year: As above for adults.

Children under the age of 1 year: Not for use in children under one year of age.

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 in the product.

Do not use on eczematous conditions.

Not for use in children under one year of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

For external use only.

Not for use around eyes, ears, nose or mouth. If contact is made, wash thoroughly with cold water. If swallowed, wash out mouth and drink plenty of water or milk. Consult a healthcare professional.

If contact is made with eyes, wash thoroughly with cold water. Consult a healthcare professional. Not for use on large areas of the body or on sensitive skin.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

There are no known drug interactions with topical chloroxylenol

4.6 PREGNANCY

No effects during pregnancy are anticipated, since systemic exposure from topical chloroxylenol use is negligible. As with all medicines, this product should be used with caution during pregnancy.

4.6.2 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.

4.6.3 FERTILITY

No data on human fertility are available

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Chloroxylenol has no or negligible influence on the ability to drive and use machinery.

4.8 UNDESIRABLE EFFECTS

Adverse events which have been associated with chloroxylenol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ($\geq 1/10$); Common ($\geq 1/100$ and $< 1/10$); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ 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, contact dermatitis, skin discolouration, application site burn

4.9 OVERDOSE SYMPTOMS

Topical application of undiluted chloroxylenol can cause skin burning.

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.

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

5.1 PHARMACODYNAMICS PROPERTIES

Pharmacotherapeutic Group: Dermatologicals, Antiseptics and disinfectants; Phenols and derivatives; Chloroxylenol

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 concentrations 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 metabolized in the body probably by the liver and is rapidly excreted mainly in the urine as sulphate and glucuronide conjugates. It has low systemic toxicity

5.3 Preclinical safety data

There are no preclinical safety data

6. PHARMACEUTICAL PARTICULARS

List of excipients

Isopropyl alcohol

Pine oil

Castor oil

Caramel colour.

a. INCOMPARTIBILITY

Not Applicable.

6.3. Shelf life

2years

6.4. Special precautions for disposal <and other handling

Store at room temperature.

Do not freeze.

Keep all drugs in a safe place. Keep out of the reach of children and pets.

Throw away unused or expired. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area

6.5 NATURE AND CONTENT OF CONTAINER

250ml and 500ml Transparent HDPE plastic bottle, with White HDPE plastic cap.

6.6 SPECIAL CONDITION FOR DISPOSAL

Keep all drugs in a safe place. Keep out of the reach of children and pets.

Throw away unused or expired. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

7.0 APPLICANT/MANUFACTURER

Applicant:

CORMART NIGERIA LIMITED.

Manufacturer:

CORMART NIGERIA LIMITED.

Address:

Km 51, Lagos- Ibadan Expressway, Ileke Town Junction, Obafemi Owode LGA, Ogun State.

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