

## **1. NAME OF THE MEDICINAL PRODUCT**

Galways Antibacterial Handwash

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<b>Active ingredient</b>	<b>% w/v</b>
Chloroxylenol	0.5

For the full list of excipients, see section 6.1

## **3. PHARMACEUTICAL FORM**

Cutaneous Solution

A clear blue aqueous detergent antiseptic solution with a characteristic fragrance.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

An antimicrobial preparation for hand disinfection.

### **4.2 Posology and method of administration**

For external use only.

Ensuring the cap is tight, turn the pump clockwise to open. Press pump down to dispense liquid onto moistened hands. Rub hands together for at least 30 seconds ensuring total coverage with lather not forgetting nails and thumbs. Rinse well with water.

### **4.3 Contraindications**

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

### **4.4 Special warnings and precautions for use**

For external use only.

Avoid contact with eyes. In case of eye contact, flush with plenty of water.

Not for use on large areas of the body or on sensitive skin.

Do not swallow. If swallowed, seek immediate medical help and show container or label.

Keep out of the sight and reach of children.

### **4.5 Interaction with other medicinal products and other forms of interaction**

Not applicable.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy**

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.

#### 4.7 Effects on ability to drive and use machines

Not applicable.

#### 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, dermatitis contact <sup>1</sup> , skin discolouration, application site burn

#### Description of Selected Adverse Reactions

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

#### 4.9 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 Pharmacodynamic properties

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 Galways Antibacterial Hand wash.

#### 5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium Lauryl Sulphate  
Sodium Chloride  
Cocamide Dea  
Cocamido Propyl Betaine  
Glycerin  
Sodium Benzoate  
Citric Acid  
Brilliant Blue  
Fragrance  
Deionised Water

### **6.2 Incompatibilities**

Not applicable to a topical formulation.

### **6.3 Shelf life**

Three years.

### **6.4 Special precautions for storage**

Store below 30°C. Protect from direct sunlight.

### **6.5 Nature and contents of container**

Plastic bottle made of polyethylene with plastic Dispenser Pumps with transparent dip tube.  
Pack sizes: 250 ml, 500 ml

### **6.6 Special precautions for disposal and other handling**

For external use only.

## **7. APPLICANT/MANUFACTURER**

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