

## 2. SUMMARY PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**GERMOL ANTISEPTIC LIQUID 50,100,250,500,1000 ML**

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	%
Water	65.43 %
Castor oil	15.00 %
Isopropyl alcohol	8.00 %
Pine oil	7.50 %
Chloroxylenol	4.0 %
Colour (Caramel)	0.07%

### 3. PHARMACEUTICAL FORM

Topical Solution

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Germol Antiseptic Liquid is indicated for:

- i) As an antiseptic and germicide prior to injection, surgery, urinary catheterization
- ii) Treatment of cuts, wounds, abrasion, burns
- iii) Pre-operation use
- iv) Dressings
- v) Post operation application to the incision
- vi) Catheterization & cystoscopy
- vii) Treatment of acne
- viii) Dental mouthwash – Gingivitis, Plaque & Oral candidiasis
- ix) Obstetrics: For the skin & gloved hands, forceps & vaginal examination

#### 4.2 Posology and method of administration

Route: Topical application

For adults and children 2 years of age and older

Apply a small amount of this product on the area 1 to 3 times daily

Condition of Administration: Clean the affected area.

May be covered with a sterile bandage. If bandaged, let dry first. Or apply as required.

#### 4.3 Contraindications

Germol Antiseptic Liquid is contraindicated to those who are hypersensitive to any of the component of the application. Avoid use on the brain meninges, middle ear and other sensitive tissues.

#### 4.4 Special warnings and precautions for use

For external use only. Keep out of reach of children. Avoid storing at excessive heat.

Do not use for longer than one week unless directed by a doctor.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance.

#### WARNINGS

Do not use in the eyes or apply over large areas of the body.

In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor. Stop use and consult a doctor if the condition worsens or if symptoms persist for more than seven days or clear up and occur again within a few days.

If redness, irritation, swelling or pain persists or increases, or if infection occurs, discontinue use and consult physician

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

None on topical application

#### 4.6 Pregnancy and lactation

Not applicable

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

Not applicable

#### 4.8 Undesirable effects

Not applicable

#### 4.9 Overdose

In case accidentally swallow, contact your physician immediately. In case of accidentally penetration into the eye wash the eye with sufficient lukewarm water.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

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 Germol antiseptic liquid.

#### 5.3 Preclinical safety data

None known

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Pine oil, Castor oil, Color Caramel & Isopropyl alcohol.

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

None

### 6.5 Nature and contents of container

50,100,250,500,1000 ml PET bottle

### 6.6 Special precautions for disposal and other handling

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

## 7. MARKETING AUTHORISATION HOLDER

Shalina Healthcare DMCC,

30<sup>th</sup> Floor, Almas Tower, Jumeirah Lakes Towers, Dubai, UAE.

**Signature of Applicant**

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**Designation**

:

**Authorized Signatory**

**Full Name**

:

**Gauri Amerkar**

**Date**

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**17.11.2023**