MAGZO
PHARMACEUTICAL & LABS LTD
ADDRESS:No 25, Crestfield Avenue, Peace Estate, Gama Kwari, Jaba,
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SUMMARY OF PRODUCT CHARACTERISTICS MAGZOL (ANTISEPTIC DISINFECTANT)

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SUMMARY OF PRODUCT CHARACTERISTICS MAGZOL (ANTISEPTIC DISINFECTANT)

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SUMMARY OF PRODUCT CHARACTERISTICS MAGZOL (ANTISEPTIC DISINFECTANT)

1. Name of the medicinal product

Magzol Antiseptic Disinfectant 4.8% w/v Concentrate for Cutaneous Solution

2. Qualitative and quantitative composition

Label Claim:	
Chloroxylenol	4.8 % w/v
Pine oil (contains d-limonene and benzyl alcohol)	12% w/v

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Concentrate for cutaneous solution.

Clear yellow liquid with pine oil odour, free from particulate matter.

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

Posology

(a) Medical uses

For cuts, bites, abrasions and insect stings: wash the area with one tablespoonful of Magzol 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 Magzol diluted in two pints of warm water.

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For dandruff: one tablespoonful of Magzol 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 Magzol 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.
Apply gently with a pad of cotton wool to the affected parts as required.

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.
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.

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

4.6 Fertility, pregnancy and lactation
Pregnancy

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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

4.7 Effects on ability to drive and use machines

None known.

4.8 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, skin discolouration, application site burn

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.

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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

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

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toxicity, even at dosage levels many times higher than those likely to be absorbed during normal usage of Magzol Liquid Antiseptic.

5.3 Preclinical safety data
No data available.

6. Pharmaceutical particulars
6.1 List of excipients
Isopropyl alcohol
Terpenol
Methyl Paraben
Propyl Paraben
Sunset Yellow
Water

6.2 Incompatibilities
None known

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container

Bottle:	PET
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	250ml, 750ml

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6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder
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