SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF MEDICINAL PRODUCT

SANITAL Disinfectant Germicide 6%

2. GENERIC NAME

Phenol

3. QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol- 7ml Lysol – 2ml Deionized Water q.s. 100ml

4. PHARMACEUTICAL FORM

Liquid

5. CLINICAL PARTICULARS

I. Therapeutic indications

SANITAL Disinfectant Germicide is an effective disinfectant against Gram-positive and Gram-negative micro-organisms.

It is used for general disinfection purposes in hospitals, homes, offices etc. and cleaning of poultry/farms, animal housing and gutters in recommended dosage. It is also used for bathing pets in the recommended dosage.

II. Posology and method of administration

For Personal Hygiene: Add 4 caps of the product in 1 Liter of the water.

Spraying Sickroom & Nursery: Dilute at 10%

Water Closet/Drain Sink: Pour a liter undiluted into the drains.

Gutters: Dilute 1 Liter to 5 Liters of water

Cleansing and Disinfection of infected linens: Dilute at 10% and soak for 10

minutes.

Poultry/Farms/Animal Housing: Dilute 1 Liter to 5 Liters of water.

Bathing Pets: 1 Liter per 10 Liters of water.

III. Contraindications

Hypersensitivity to Phenol.

Prolonged use of high concentrations of the product may result in skin irritation.

IV. Special warnings and precautions for use

This preparation should not be applied to the skin undiluted because of its corrosive properties.

Avoid direct contact with mucous membranes as it can cause eye irritation.

Due to the local anaesthetizing properties of phenol, skin burns may be painless.

This preparation is for external use only.

Keep all medicines out of the reach of children.

V. Interaction with other medicinal products and other forms of interaction

No interactions were observed or reported with this product.

VI. Pregnancy and Lactation

Prenatal exposure to phenol has been associated with reductions in fetal weight and viability, and with an increase in unusual neurological symptoms.

Epidemiological studies have not associated prenatal exposure to phenol with birth defects in human infants.

VII. Effects on the ability to drive and use machines

None Known

VIII. Undesirable effects

SANITAL Disinfectant Germicide has the potential to induce eye irritation and should not come into contact with bare eyes.

In the event of ingestion, it can lead to symptoms such as nausea, vomiting, bronchial irritation, abdominal pain, or even a potential collapse.

IX. Overdose

In situations where it is ingested, stomach lavage should be performed.

6. PHARMACOLOGICAL PROPERTIES

I. Pharmacodynamics properties

SANITAL Disinfectant Germicide belongs to the therapeutic group: D08A – Dermatological, Antiseptics and Disinfectants.

It is active against a wide range of micro-organisms including some fungi and viruses, but is only slowly effective against spores. Phenol is also used in skin disinfection and to relieve itching.

II. Pharmacokinetic properties

Absorption: It is easily absorbed from the gastrointestinal tract, through

intact skin and mucous membranes.

Metabolism: In the liver, it undergoes metabolism into phenyl glucuronide and

phenyl sulfate, and in some cases, it is oxidized to catechol and quinol before undergoing further conjugation, although only in

small quantities.

Excretion: Via urine as metabolites

III. Preclinical safety data

Phenol may be fatal if swallowed, inhaled or absorbed through the skin.

7. PHARMACEUTICAL PARTICULARS

I. List of excipients

Lysol

Deionized Water

II. Incompatibilities

None Known

III. Shelf life

36 Months

IV. Special precautions for storage

Store below 30 °C in a cool dry place

V. Nature and contents of the container

150ml HDP Plastic with tamper-proof cover.

1 Liter HDP Plastic with tamper-proof cover.

4-litre white HDP Plastic with tamper-proof cover.

VI. Special precautions for disposal

None

8. <APPLICANT/MANUFACTURER>

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