

SUMMARY OF PRODUCT CHARACTERISTICS, SANITAL PLUS

1. NAME OF THE MEDICINAL PRODUCT

SANITAL PLUS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sanital contains Chlorhexidine Gluconate 0.3% w/v + Cetrimide 3% w/v

Demineralized water

3. PHARMACEUTICAL FORM

Product description: Colourless liquid with characteristic odour which is soluble when dropped in water.

4. Clinical particulars

4.1 Therapeutic indications/Application

Sanitization of Surgical table, Food preparation and service areas.

Use in dairy, food processing, packaging and catering establishment.

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

Food processing and hospital areas:

Add to water and apply to area to be cleaned with mop, with scrubbing, thereafter rinse off with water.

Adults:

For cuts, bites, abrasions and insect stings: Wash the affected area with product at 0.02 to 0.1% dilution

A 0.02 to 0.05% solution use as a vaginal douche..

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 Phenol 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 Phenol.

4.6 PREGNANCY

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

4.6.2 BREAST-FEEDING

Topical maternal application of Phenol or their presence as a preservative in pharmaceuticals would not be expected to cause any adverse effects in breastfed infants.

4.6.3 FERTILITY

No data on human fertility are available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 UNDESIRABLE EFFECTS.

Phenol is considered acutely toxic. Exposure to the toxic chemical may produce side effects such as rashes, allergic reactions, itching, redness, swelling, blisters, skin peeling, fever, wheezing, tightness in the chest or throat, trouble breathing or talking, unusual hoarseness, mouth/face/lips/tongue/throat swelling. Ingestion of BAK may cause abdominal pain, nausea, vomiting, burning sensations, diarrhea, shock and/or collapse.

Long-term exposure may cause asthma, chronic dermatitis, and other immune system disorders.

4.9 OVERDOSE

SYMPTOMS

Topical application of undiluted phenol 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; such as

benzalkonium chloride 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

5.3 Preclinical safety data

There are no preclinical safety data

6.0 PHARMACEUTICAL PARTICULARS 6.2 INCOMPATIBILITY

List of excipients

Demineralized water

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 SPECIAL CONDITION FOR DISPOSAL

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7. APPLICANT/MANUFACTURER

***Nino Pharm & Chem Co. Ltd
1, Nino Crescent Era Town,
Off Badagry Expressway,
Ojo LGA Lagos.***